Usermanual

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This user manual is intended to give detailed information for end users of the Analyticon Biotechnologies AG ‘Hemolyzer 5’ optical hematology analyzer.

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This manual was written with the intention to give the most precise and up-to-date, detailed description of operation and use of the analyzer for laboratory purposes.

Despite careful revision and multiple grammar and content control, mistakes can still be present in this manual. Analyticon may from time to time issue errata, or a new revision of the manual. Would you find things unclear, please contact your service engineer for assistance.

Descriptions contained herein are relevant to ‘Hemolyzer 5’, software versions (latest available at the publication of the manual):

- User (graphical) interface sw: 1.1.623;
- OPN (pneumatic) sw: 1.1.623;
- Firmware: 2.66 (1125)
- PIC sw: 1.8
- Laser sw: 3.5
- TCU sw: 3.41

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1 For Your Safety

1.1.1 Who Should Use This Manual

This user manual is intended for clinical laboratory professionals using the Analyticon 'Hemolyzer 5' automated hematology analyzer. The manual includes information about the operation and user interface of the 'Hemolyzer5' analyzer.

It also contains basic steps necessary to perform the setup procedures to tailor the operation of the analyzer to the requirements of your laboratory.

This manual also describes daily routine maintenance requirements to keep your analyzer functioning properly.

1.1.2 Special Symbols Used In This Manual

Label	Meaning	Explanation
	Biohazard	Blood samples and analyzer waste are potentially infectious materials.
	Corrosive	Reagents may cause corrosion or skin irritation.
	Warning	General warning of possible hazard conditions.
	Sharp needle warning	The sampling needle may be a hazard to the operator.

1.1.3 General Precautions

	The analyzer weighs 35kg (~77lbs).Please do not attempt to move it alone. The analyzer should always be moved by two persons holding the analyzers by its sides in an upright position.
	Always use safe lifting procedures when lifting the analyzer.
	Make sure to retain the original packaging material for safe transportation and storage in the future.
	To prepare the analyzer for shipping, storage or extended periods of inactivity, please drain the reagents and repackage the 'Hemolyzer 5' in its original packaging. Do not expose the 'Hemolyzer 5' to direct sunlight, extreme temperature or humidity (>80%).
	The analyzer operates with chemically and biologically active reagents. Physical contact with these reagents should be avoided. Please read reagent descriptions carefully for possible emergency actions.

	To ensure reliable operation and reliable results: • Only human blood samples should be analyzed • Only genuine Analyticon reagents should be used • Required maintenance (user and service level) should be performed as recommended in this manual • Only Analyticon certified service personnel should perform service actions • Only genuine Analyticon service materials and spare parts should be used
	Genuine reagents and service materials and spare parts are available from Analyticon.
	Only Analyticon certified service personnel that have successfully completed the 'Analyticon Hemolyzer 5 Service Training' program are qualified to service the 'Hemolyzer 5' analyzer.
	Before operating the 'Hemolyzer 5' analyzer, all operators should complete a 'Analyticon Hemolyzer 5 Operator Training' program. This program is offered by Analyticon or by Analyticon certified service personnel.
	Replacement materials or spare parts (tubes, valves, etc.) which might have been in contact with human blood or reagents should be handled as a potentially biologically hazardous and chemically dangerous material. All applicable laws and regulations must be observed in the handling and disposal of these materials.
	The 'Hemolyzer 5' is designed for laboratory operation. Mobile operation is not supported. Operate 'Hemolyzer 5' within the ambient temperature range described in section 1.1.4.
	The IVD equipment complies with the emission and immunity requirements described in relevant part of the IEC 61326 series.
	This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
	Electromagnetic environment should be evaluated prior to operation of the device.
	This analyzer contains electronic components. Please handle electronic waste adhering to local or federal regulations.

1.1.4 Environmental Factors

Operate the 'Hemolyzer 5' analyzer within the ambient temperature range of 15-30°C (59-86 °F) and a relative humidity range of 10% - 80%. The optimum operating temperature is 25°C (~77°F).
Avoid exposing the 'Hemolyzer 5' analyzer to direct sunlight or to extreme high or low temperatures.
If the 'Hemolyzer 5' analyzer was subjected to extreme temperatures during shipment or storage, the analyzer must be placed for at least one hour in a room whose temperature is within the operational range before installation or use.
Reagents should be stored at a temperature range of 15-30°C (59-86 °F).
The analyzer should be placed in a well-ventilated location.
Operation at an altitude above 3000 meters (9800 ft) is not recommended.

1.1.5 Electrical Requirements

The analyzer should only be operated from a wall outlet meeting these power input requirements:

- 100-127VAC/200-240VAC; 47Hz to 63Hz
- Power Consumption: maximum 400 VA

Please ensure that the wall outlet is also capable of supplying the power consumption of any additional devices (such as a printer).

Only the power cord supplied with the instrument should be used. Avoid using extension cords. The 'Hemolyzer 5' analyzer comes with a power cord appropriate for your power system. Proper use of the appropriate power cord assures adequate grounding of the system. If the power network is not reliable, contact your representative for options such as the installation of an external UPS module.

	Failure to properly ground the 'Hemolyzer 5' bypasses important safety features and may result in electrical hazard.

The instrument should not be placed near potentially interfering devices capable of emitting radio frequencies (e.g. radio or television transmitters/receivers, radars, centrifuges, X-ray devices, fans, etc.).

This analyzer is designed to be safe for transient voltages to INSTALLATION CATEGORY II and POLLUTION DEGREE 2.

1.1.6 Space Requirements

It is important to install the instrument in a suitable location. A poor location can adversely affect its performance.

Select a well-ventilated location near a power source and close to a suitable drain.

Place the unit on a clean, level surface. Leave at least 0.5 m (18 inches) space on both sides and above the instrument to access pneumatics. A minimum of 0.2 m (8 inches) must be maintained between the rear panel and the wall to allow for heat dissipation and tube clearance.

Ensure there is enough clearance in front of the 'Hemolyzer 5' analyzer to open the front panel. Allow enough space if you want to use optional external keyboard, mouse or bar code reader.

Your selected location should allow placement of the reagents in an unobtrusive location below the laboratory bench that the instrument is placed on, or on the same surface. Placement below the laboratory bench also allows for storage of a spare set of reagents. Never place the reagents above the 'Hemolyzer 5' analyzer.

See Figure 1 and Figure 2 for more information about proper analyzer location and clearance.

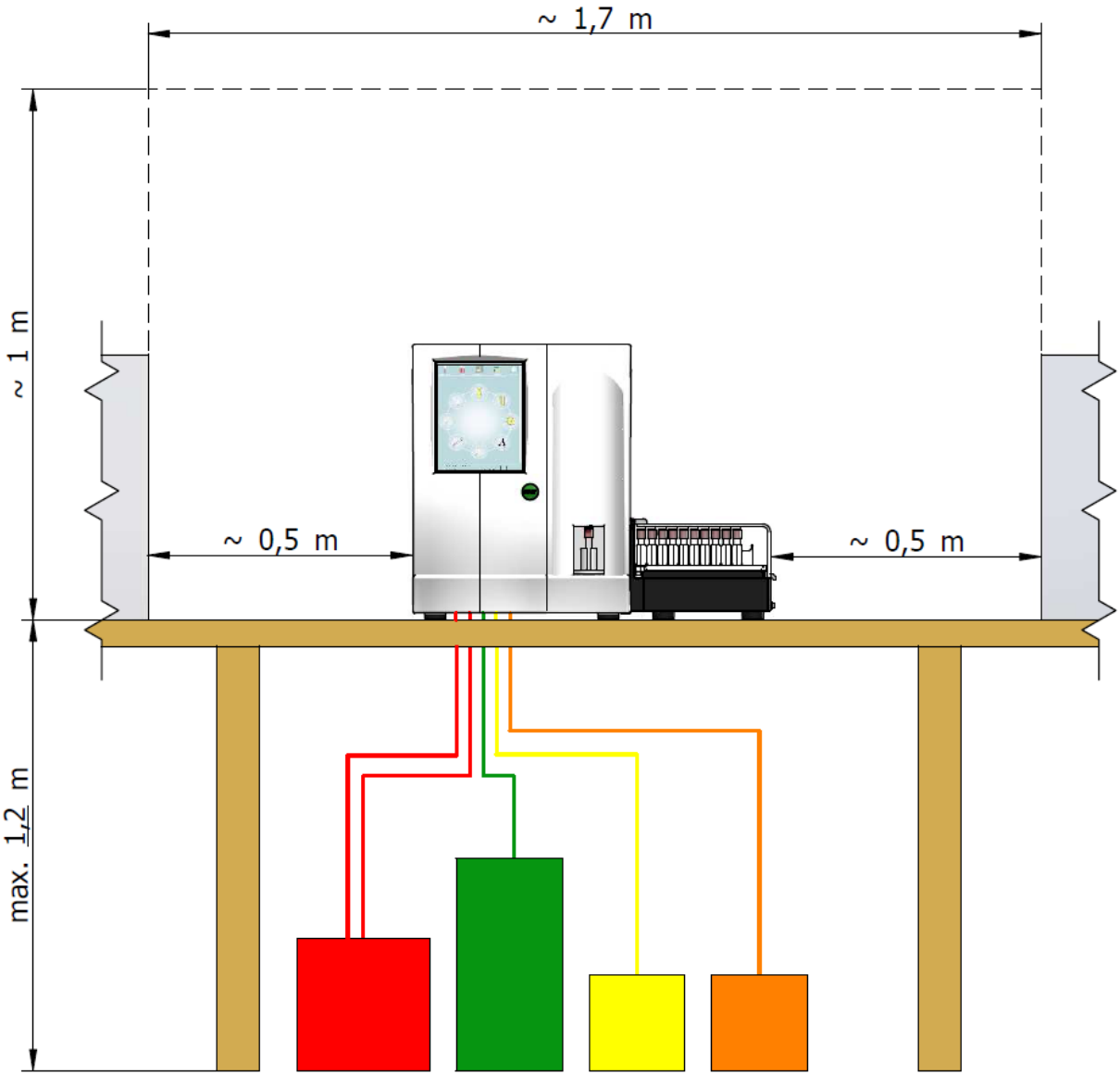


Figure 1. Hemolyzer 5 with Autosampler Space Requirements

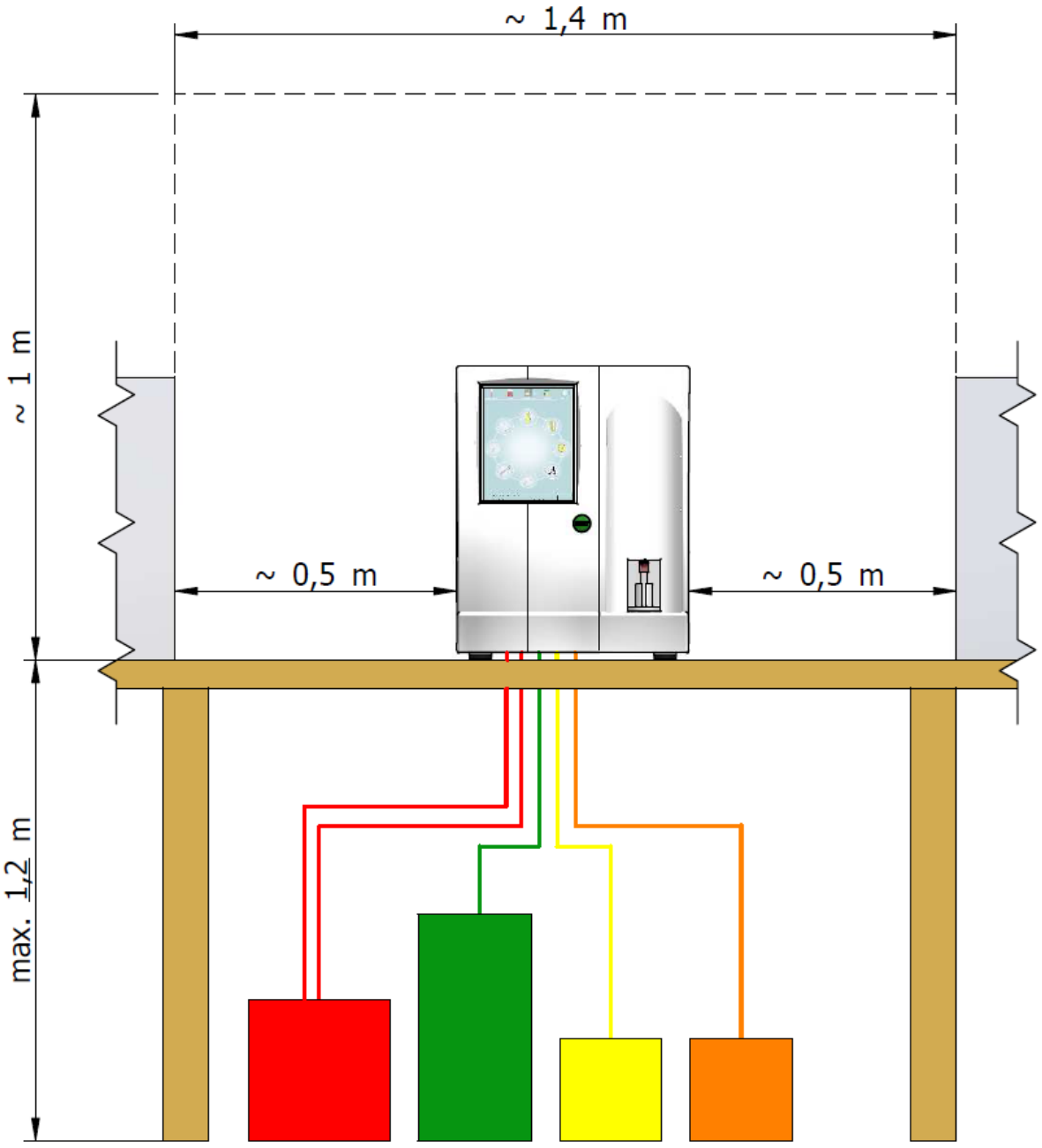


Figure 2. Hemolyzer 5 Without Autosampler Space Requirements

1.1.7 Weight Requirements

The 'Hemolyzer 5' analyzer weighs 35 Kg (77 lb) without the Autosampler. The 'Hemolyzer 5' with optional Autosampler weighs 47Kg (104 lb). Adding an external keyboard, documents etc. can bring the total weight up to 60 Kg (132 lb). If you decide to store the reagents on the same surface, then the combined weight can reach 100 Kg (220 lb).

Please select a table, laboratory shelf, or other location which can support the weight of the 'Hemolyzer 5' with accessories and is free from vibration.

	To allow reliable operation and to provide a safe working environment, make sure that the table supporting the unit is stable enough to carry the weight of the instrument and accessories.

1.1.8 Waste Disposal

'Hemolyzer 5' analyzer waste contains human blood and reagents that are chemically and biologically active, and should be considered to be a potential infection and biohazard threat. Safe laboratory practices must be followed including the use of personal protective when operating the 'Hemolyzer 5' and handling blood, reagents, and waste.

1.1.9 Known Limitations

The 'Hemolyzer 5' is not intended for analysis of animal blood samples. Anti-coagulated and homogenized human blood samples must be free from contamination.

Blood samples must be analyzed within 12 hours of venipuncture.

1.1.10 Emergency Situations

Always follow all applicable laws and regulations with regard to emergency situations.

If the 'Hemolyzer 5' needs to be powered off due to an emergency situation (like fire, thunderstorm etc.), follow the procedures in chapter 6.3.4.

	In case of fire, do not use water to extinguish the fire unless the 'Hemolyzer 5' is disconnected from the electrical network!

2 Product Support

Your sales representative is trained and qualified to answer questions about applications and the operation of the ‘Hemolyzer 5’ analyzer. If you have additional questions regarding the ‘Hemolyzer 5’, please ask for manufacturer support through your sales representative.

Analyticon makes every effort to provide excellent support and up to date information and services regarding the ‘Hemolyzer 5’ analyzer. For further support or questions please contact us: support@analyticon-diagnostics.com

3 Installation

Your Analyticon certified service engineer will perform the initial installation of the 'Hemolyzer 5' analyzer and train you and selected laboratory personnel on the proper use and maintenance of the analyzer.

The certified service engineer will also train you how to use your analyzer. You'll also be explained about necessary maintenance actions.

3.1 Package contents

3.1.1 The 'Hemolyzer 5' Analyzer Package

After opening the 'Hemolyzer 5' analyzer packaging, you will find an accessory box. The analyzer is in a plastic bag in between cushioning protective material. After opening the bag, remove the desiccant packs. The package should contain the following items:

- Accessories box on top of the analyzer, including:
- Power cord
- User Manual (this document)
- Sample tube adapter for the individual sample unit (1 pc)
- Reagent tube kit (in a plastic bag, with special caps)
- Plastic waste container
- Cardboard box for the waste container
- "Preparing for shipment" tube kit
- 'Hemolyzer 5' analyzer final check report
- The 'Hemolyzer 5' analyzer

Please inform your Sales Representative if any item is missing or damaged. Retain the original 'Hemolyzer 5' analyzer packaging for future transportation and storage.

3.1.2 The Autosampler Package

The Autosampler is an optional unit that attaches to the Hemolyzer 5. If the optional Autosampler unit was ordered, package should contain the following items:

- Autosampler unit
- A sample tray
- 10 pieces sample racks
- Autosampler final check report

Please inform your sales representative if any item is missing or damaged. Retain the original Autosampler packaging for future transportation and storage.

4 General Overview and Principles of Operation

4.1 General Overview

The 'Hemolyzer 5' is a fully automated high quality hematology analyzer for *in vitro* diagnostic use in clinical laboratories. It provides precise and accurate 5-part differential measurement using a laser based optical measurement technology.

The 'Hemolyzer 5' analyzer uses the Coulter method for measurement of leukocytes (WBC), erythrocytes (RBC) and platelet (PLT) concentrations. Measurement of the hemoglobin (HGB) content of red blood cells is accomplished by photometric measurement technology. Five part leukocyte differentiation (LYM%, MON%, NEU%, EOS%, BAS%) is accomplished using optical laser-based flow cytometric technology.

A vivid color touch screen display is featured with an intuitive, informative, and attractive user interface. A START button allows one-touch operation for ease of use.

The 'Hemolyzer 5' analyzer's unique software system supports the use of many commonly used external printers with its USB connections. The 'Hemolyzer 5' internal database is capable of storing 100,000 patient, QC, and calibration result records including flags and graphical scatter diagrams and histograms. The system software is field-upgradeable to ensure up-to-date operation.

An automatic optional Autosampler is available (sold separately) for automatically processing up to 100 sample tubes for increased laboratory efficiency. The system software supports a variety of flexible LIS download techniques for efficient integration into laboratory workflow.

The 'Hemolyzer 5' features advanced Ethernet LIS connectivity using the HL7 protocol in addition to standard serial interfaces, providing the clinical laboratory with flexible connectivity options.

4.1.1 Measured Parameters

'Hemolyzer 5' determines 24 hematology parameters including 5-part WBC differential. The instrument requires 110 µl of whole blood-sample in Closed- and Open-vial mode. Cycle time is 60 seconds.

Parameter	Symbol	Measurement method
White Blood Cell count	WBC	Impedance measurement
Lymphocyte count	LYM	Calculated
Monocyte count	MON	Calculated
Neutrophil count	NEU	Calculated
Eosinophil count	EOS	Calculated
Basophil count	BAS	Calculated
Lymphocyte percentage	LYM%	Optical measurement
Monocyte percentage	MON%	Optical measurement
Neutrophil percentage	NEU%	Optical measurement
Eosinophil percentage	EOS%	Optical measurement
Basophil percentage	BAS%	Optical measurement
Red Blood Cell count	RBC	Impedance measurement
Hemoglobin	HGB	Photometric measurement
Hematocrit	HCT	Calculated
Mean Corpuscular Volume	MCV	Derived

Parameter	Symbol	Measurement method
Mean Corpuscular Hemoglobin	MCH	Calculated
Mean Corpuscular Hemoglobin Concentration	MCHC	Calculated
Red Blood cells Distribution Width	RDWcv	Derived
Red Blood cells Distribution Width	RDWsd	Derived
Platelet count	PLT	Impedance measurement
Mean Platelet Volume	MPV	Derived
Platelet Distribution Width** *(for Research Use Only)*	PDWcv	Derived
Platelet Distribution Width** *(for Research Use Only)*	PDWsd	Derived
Thrombocrit** *(for Research Use Only)*	PCT	Calculated
**The PDWcv, PDWsd, and PCT parameters are considered to be for Research Use Only (RUO), and will be marked by MARK MARK on the screen, printout, database, and LIS transmission.		

Table 1. 'Hemolyzer 5' Analyzer Parameters

4.1.2 Approved Reagents and Control Materials

Always use reagents, control materials and calibration materials that are recommended and approved by the manufacturer. The 'Hemolyzer 5' analyzer, control material, calibrator material and reagents are part of a system and are carefully designed and selected for optimal performance. Using unapproved reagents or controls may cause false flagging or incorrect, inaccurate results.

Only genuine Analyticon reagents may be used in the 'Hemolyzer 5' analyzer. Analyticon recommends the use of CBC-3K® control material and CBC-CAL® calibration material from R&D Systems®. These materials have been specifically assayed for use in the 'Hemolyzer 5' analyzer.

R&D Systems can be reached at:

R&D Systems, Inc.
614 McKinley Place N.E., Minneapolis, MN 55413
Tel: Customer Service / Sales: 800-428-4246
Fax: Customer Service / Sales: 612-379-6580

For additional details about these materials, please contact the manufacturer directly.

4.1.3 Genuine Analyticon Reagents

Only use the genuine Analyticon reagents below to ensure proper performance of the 'Hemolyzer' analyzer. Reagents are manufactured and provided by Analyticon Biotechnologies AG, and are for *in vitro* diagnostic use only.

	If the eyes or skin come into contact with any of the reagents, flush abundantly with water. If ingested, drink water immediately and seek medical attention.

4.1.3.1 Hemolyzer-Diluent

Description	Multiple micro-filtered, particle free buffered isotonic solution, containing stabilizers, special additives and preservatives.
Application	Quantitative and qualitative determination of RBC, WBC, PLT and HGB concentration.
Appearance	Colorless, odorless solution.
Shelf-life	36 months
Open bottle stability	120 days
Storage	Between +15 °C and +30 °C. (~59-86 °F)
Analyticon reagent code	HE3201 (20 L)
Color code	Green

Table 2. Hemolyzer-Diluent Information

The product is environmental-friendly, since does not contain azide nor cyanide

4.1.3.2 Hemolyzer-5-Lyser

Description	Multiple micro-filtered, particle free reagent solution, containing lysing detergents, stabilizers, leucoprotective components, special additives and preservatives.
Application	Quantitative and qualitative determination of WBC, 5diff and HGB concentration.
Appearance	Colorless solution, foaming by shaking.
Shelf-life	24 months
Open bottle stability	120 days
Storage	Between +15 °C and +30 °C. (~59-86 °F)
Analyticon reagent code	HE5101 (5 L)
Color code	Yellow

Table 3. Hemolyzer-5-Lyser Information

The product is environmental-friendly, since does not contain azide nor cyanide.

4.1.3.3 Hemolyzer-5-Diff 5p

Description	Multiple micro-filtered, particle free reagent solution, containing stabilizers, leucoprotective components, special additives and preservatives.
Application	Quantitative determination of WBC, leukocyte four-part differentiation (LYM, MON, NEU, EOS).
Appearance	Colorless, odorless solution.
Shelf-life	24 months
Open bottle stability	120 days
Storage	Between +15 °C and +30 °C. (~59-86 °F)
Analyticon reagent code	HE5201 (1 L), HE5202 (5 L)
Color code	Orange

Table 4. Hemolyzer-5-Diff 5p Information

The product is environmental-friendly, since does not contain azide nor cyanide.

4.1.3.4 Hemolyzer Hypocleaner

Description	Containing alkaline hypochlorite, special additives and preservatives.
Application	Capillaries, tubing and chambers, removing blood component precipitates.
Appearance	Slightly yellow liquid with chlorine odor.
Shelf-life	15 months.
Open bottle stability	120 days
Storage	Between +15 °C and +30 °C (~59-86 °F)
Analyticon reagent code	HE3401 (100 ml)

Table 5. Hemolyzer Hypocleaner Information

The “Hypocleaner CC” is not an online-reagent (not directly connected to the ‘Hemolyzer 5’). This reagent is aspirated from a sample tube into the ‘Hemolyzer 5’ directly.

4.2 Principles of Operation

The 'Hemolyzer 5' analyzer uses a combination of methods to provide measurement results:

- Volumetric impedance (the Coulter method) is used to determine the cellular concentrations and volume distributions of leukocytes (WBC), erythrocytes (RBC), and platelets (PLT).
- Photometric measurement of light absorbance is used to determine hemoglobin (HGB) concentration.
- Optical measurement of light scattering and diffraction is used to determine five part leukocyte (LYM%, MON%, NEU%, EOS%, BAS%) differential parameters.

4.2.1 Volumetric Impedance Method

The volumetric impedance method (also known as the Coulter method) determines cellular concentrations and volume distributions of cells by detecting and measuring changes in electrical impedance when particles suspended in a conductive liquid pass through a small aperture. The method is "volumetric" because a small known volume of blood is precisely diluted with a conductive diluent and forced through the aperture at a fixed rate.

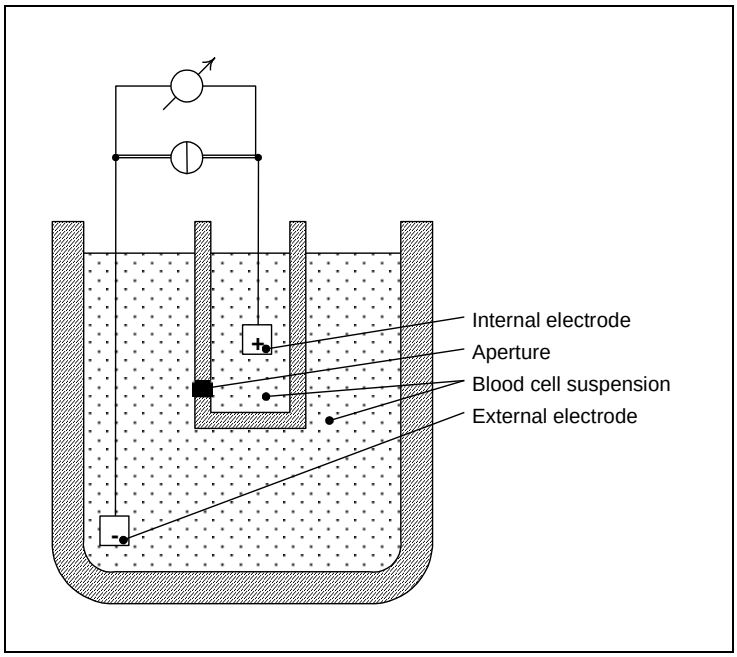


Figure 3. Volumetric Impedance Method

A constant direct current flows between the electrodes on either side of the aperture. Each cell passing through the aperture causes a change in the electrical impedance of the conductive blood cell suspension. This change is sensed by the 'Hemolyzer 5' electronics and converted to an electrical pulse. The quantity of pulses is proportional to the number of particles. The intensity of each pulse is proportional to the volume of the particle. The volume distribution diagrams of the particles result in the WBC, RBC, and PLT histograms that measured in femtoliter volume units.

Electronic discrimination allows separation of erythrocytes (RBC) and platelets (PLT). A lytic reaction lyses erythrocytes to clearly measure leukocytes (WBC).

4.2.2 Photometric Light Absorbance Method

A lysed blood sample dilution can be analyzed for hemoglobin (HGB) concentration based on its stable chromogen content. The reagent lyses the red blood cells causing the release of cellular hemoglobin. The hemoglobin concentration is measured by taking a photometric reading across the 'Hemolyzer 5' WBC chamber. The HGB measurement is calculated as the difference between and blank and a sample measurement with and without illumination to reduce the effect of liquid refraction and incident light.

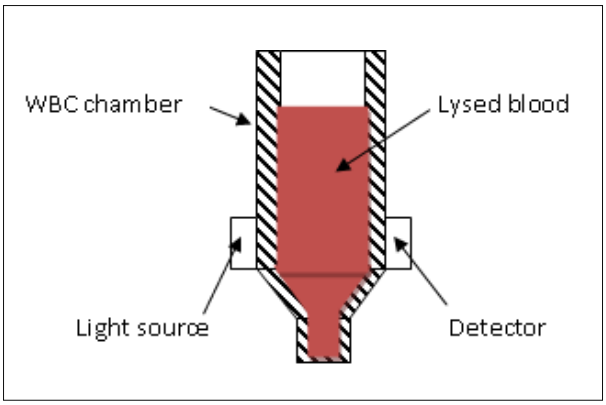


Figure 4. Photometric Light Absorbance Method

4.2.3 Optical Light Scatter and Diffraction Method

Optical measurement of light scattering and diffraction is used to determine five part leukocyte (LYM%, MON%, NEU%, EOS%, BAS%) differential parameters. An optical measuring head contains a focused laser source that is used to illuminate a stream of leukocytes (WBC) suspended in an optically clear diluent moving through a flow cell.

The cells scatter light as they flow through the path of the laser beam. An optical detector senses changes in the intensity of the scattered laser light which are proportional to the cell volume and granularity of the cell's internal structure. The 'Hemolyzer 5' electronics convert these changes to electrical pulses which are gathered and stored for analysis. Five part population discrimination is based on analysis of the two dimensional volume and granularity distribution scatter diagram.

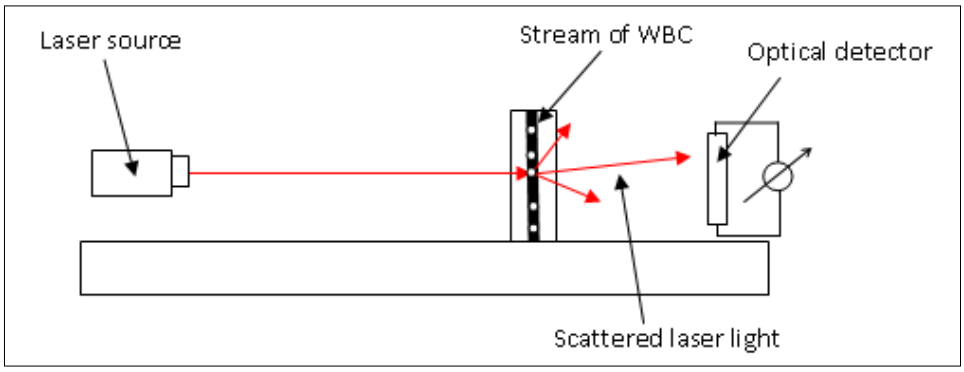


Figure 5. 'Hemolyzer 5' Optical Head Block DIagram

Cells with greater volume or size or more granularity will tend to scatter greater amounts of light. The intensity of scattered light is detected by an optical signal processing system.

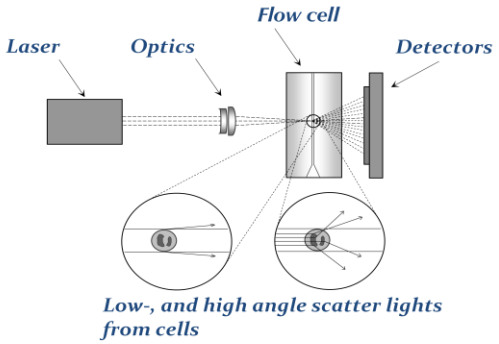


Figure 6. Optical Signal Processing System

External structure (and the size of the cell) causes lower angles of scatter, and internal granularity or complexity causes higher angles of diffraction. Both low and high angles of light scatter are captured by optical sensors, providing the 'Hemolyzer 5' analyzer with two independent measurements for each cell crossing the path of the laser beam.

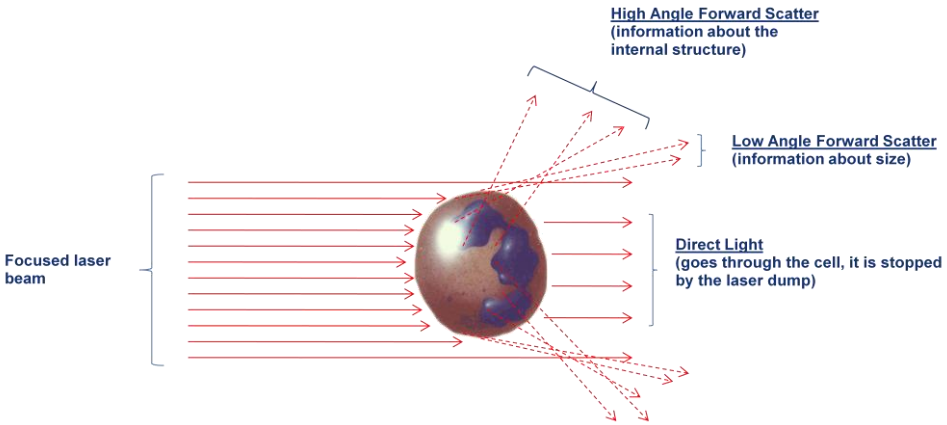

High Angle Forward Scatter
(information about the internal structure)
Low Angle Forward Scatter
(information about size)
Focused laser beam
Direct Light
(goes through the cell, it is stopped by the laser dump)

Figure 7. Cellular Light Scatter

The light scatter data are gathered and plotted as a two dimensional scatter diagram. Similar cells have similar scatter characteristics and tend to group together. This allows the analytical software to differentiate and identify the leukocyte populations and generate the 4DIFF and BASO scatter diagrams.

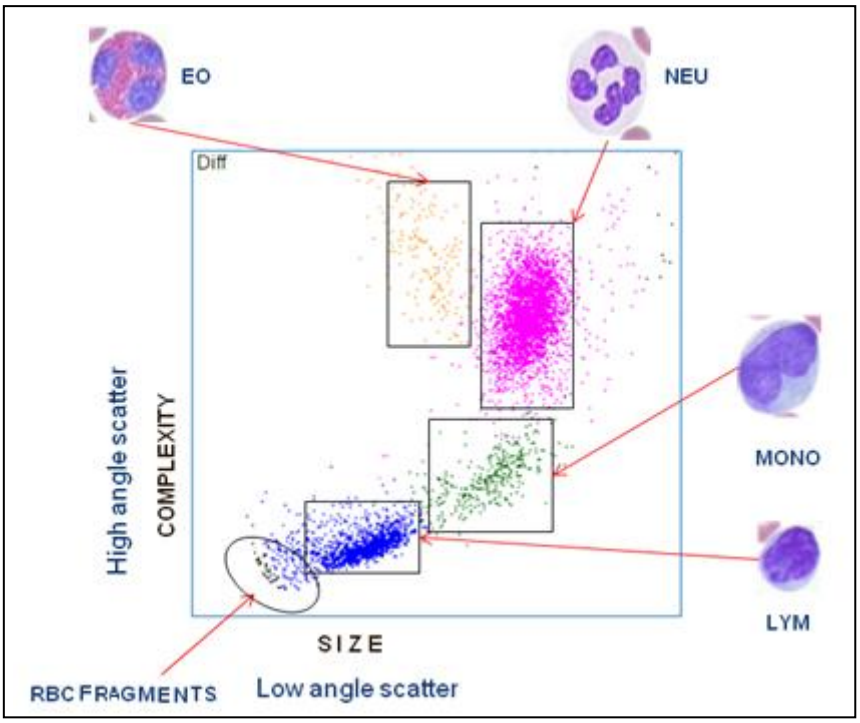


Figure 8. 4DIFF Scatter Diagram

4.3 Inside the 'Hemolyzer 5' Analyzer

Front Panel

The touch screen display is the primary user interface of the 'Hemolyzer 5' analyzer for user interactions and data entry. The LCD screen can be cleaned damp sponge and gentle detergent.

The front panel is a hinged cover that provides easy access to the shear valve, sampling needle and syringes for cleaning and maintenance. The front panel, START button, and the sample rotor can be cleaned with damp sponge and 70% ethanol.

Sample tubes are placed into a tube adapter inserted on the sample rotor for closed vial or open vial single-tube manual sample processing. The sample tube is rotated from the front of the unit into the inside of the 'Hemolyzer 5' for aspiration. This safety feature protects the operator from inadvertent contact with the aspiration needle during specimen processing.

Automatic sample processing with the optional Autosampler can be interrupted in order to run one or more stat samples with the sample rotor. Automatic processing can be resumed after stat sample processing is complete.

The START button allows easy one-hand operation of the 'Hemolyzer 5' analyzer. The color of the START button indicates the status of the 'Hemolyzer 5' analyzer. Green means the 'Hemolyzer 5' is ready to process samples, and red means the 'Hemolyzer 5' is busy. Orange means the 'Hemolyzer 5' analyzer is in a standby state.

4.3.1 Back Panel

①Power connector: the 'Hemolyzer 5' power connector should be connected to a grounded power outlet that meets the requirements listed in section 1.1.5.

②Main power switch: this is a small switch located next to the power connector. This switch turns off all electrical power to the 'Hemolyzer 5' analyzer. Leaving this switch on allows the 'Hemolyzer 5' to remain in the standby state. The switch is on when it is in the 'up' position labeled '1' and is off when it is in the down position labeled '0'.

③Standby switch: flipping this switch to the 'up' position takes the 'Hemolyzer 5' main computer out of the standby state and powers up internal analyzer components. Please note that this switch springs back to the down position when released and does not stay in the 'up' position.

Figure 10. Hemolyzer 5 Back Panel

④Hardware Key connector: this connection is used to plug in the hardware key supplied with every new package of genuine Analyticon Hemolyzer-5-Lyser reagent. A new reagent key provides the analyzer with the ability to run 700 measurements. When the measurement count has been exhausted, the 'Hemolyzer 5' analyzer stops processing samples.

⑤Reagent connectors: five color-coded tubing connectors provide connection to the reagents. There are three reagent connectors and two waste connectors.

	Green	1 connector	Hemolyzer-Diluent
	Orange	1 connector	Hemolyzer-5-Diff 5p
	Yellow	1 connector	Hemolyzer-5-Lyser
	Red	2 connectors	Waste

Table 6. Reagent Connector Color Codes

⑥Main board back panel I/O Ports: these are the back panel computers of the 'Hemolyzer 5' analyzer main computer board. They provide standard connection to peripherals such as external keyboard and mouse, printers, bar code readers.

1	PS2 Mouse port for optional mouse
1	PS2 Keyboard for optional PS2 keyboard
1	COM port for LIS
2	RJ45 Ethernet port for LIS

1	VGA port (unused)
4	USB 2.0 ports for peripherals
3	Audio jacks (unused)

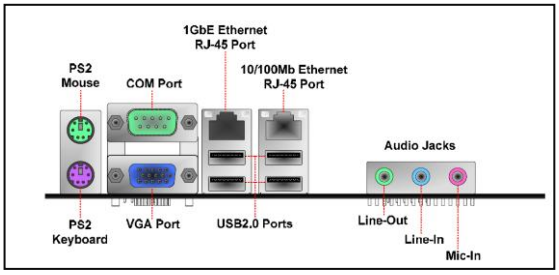


Figure 11. Main Board Back Panel I/O Ports

Avoid getting liquids on the electrical connectors. The rear panel of the analyzer should be cleaned with a cloth or sponge with 70% ethanol.

4.3.2 Left Side Assembly

To access the left or right side assemblies, the side panels must be removed. Please refer to section 15.1.3 for information about removing the side panels.

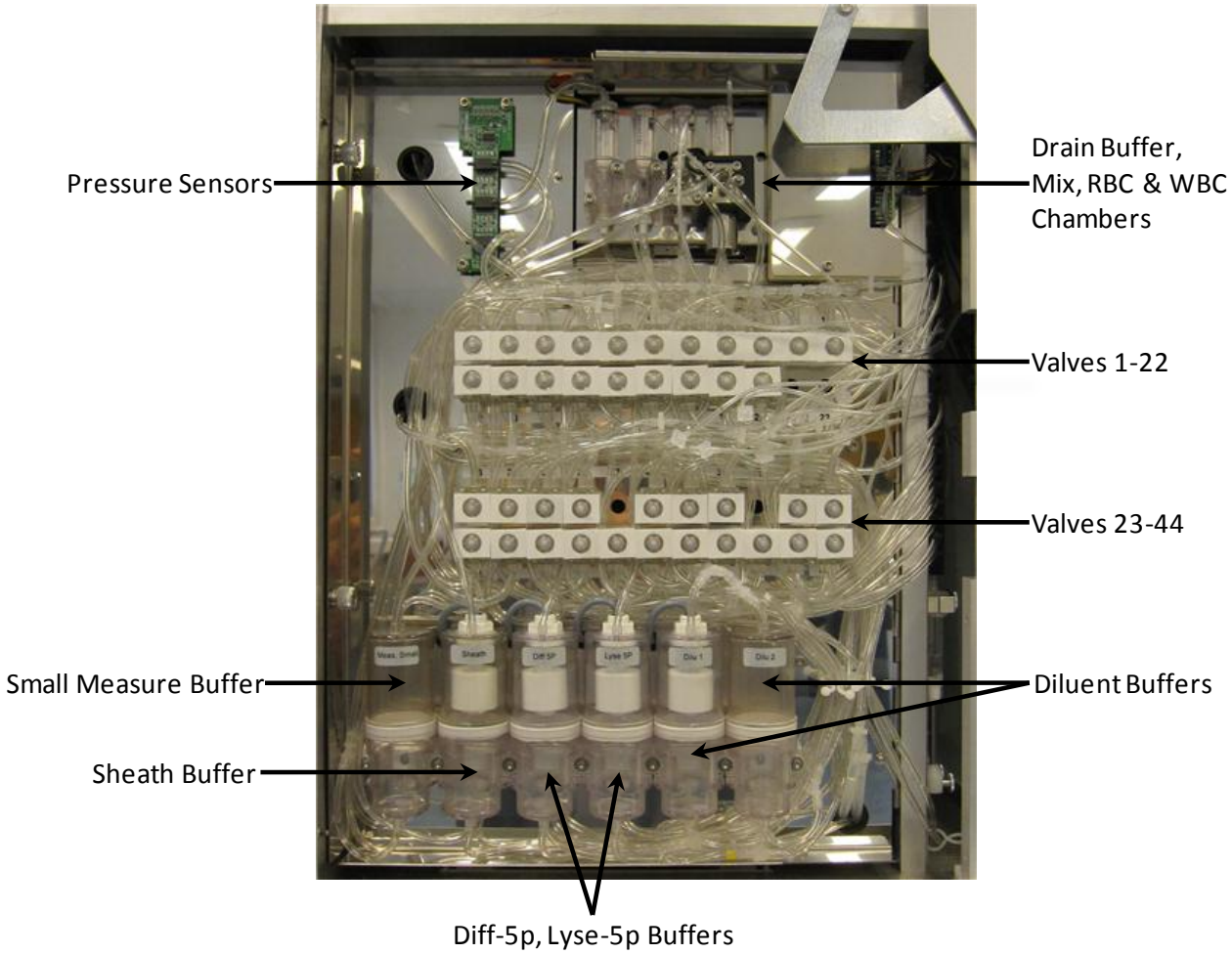


Figure 12. Left Side Assembly

- Pressure sensors measure the differential pressures of vacuum buffer for impedance base and optical measurement and empty chamber process.
- Small Measure buffer is a vacuum buffer used for impedance measurement.
- Sheath buffer is a reservoir for Hemolyzer-Diluent for optical measurements.
- Diff-5P buffer is a reservoir for Hemolyzer-5-Diff 5P reagent.
- Lyse-5P puffer is a reservoir for Hemolyzer-5-Lyser reagent.

- Diluent buffers are reservoirs for Hemolyzer-Diluents.
- Valves 1-44 connect pneumatic components to carry out dilution, reaction, measurement, and waste disposal processes.
- Drain buffer controls chamber draining procedures.
- Mix chamber performs the first step of RBC dilution.
- RBC chamber performs the second step of RBC dilution and contains the RBC aperture.
- WBC chamber performs the WBC dilution and holds the WBC aperture and HGB photometric measurement system.

4.3.3 Right Side Assembly

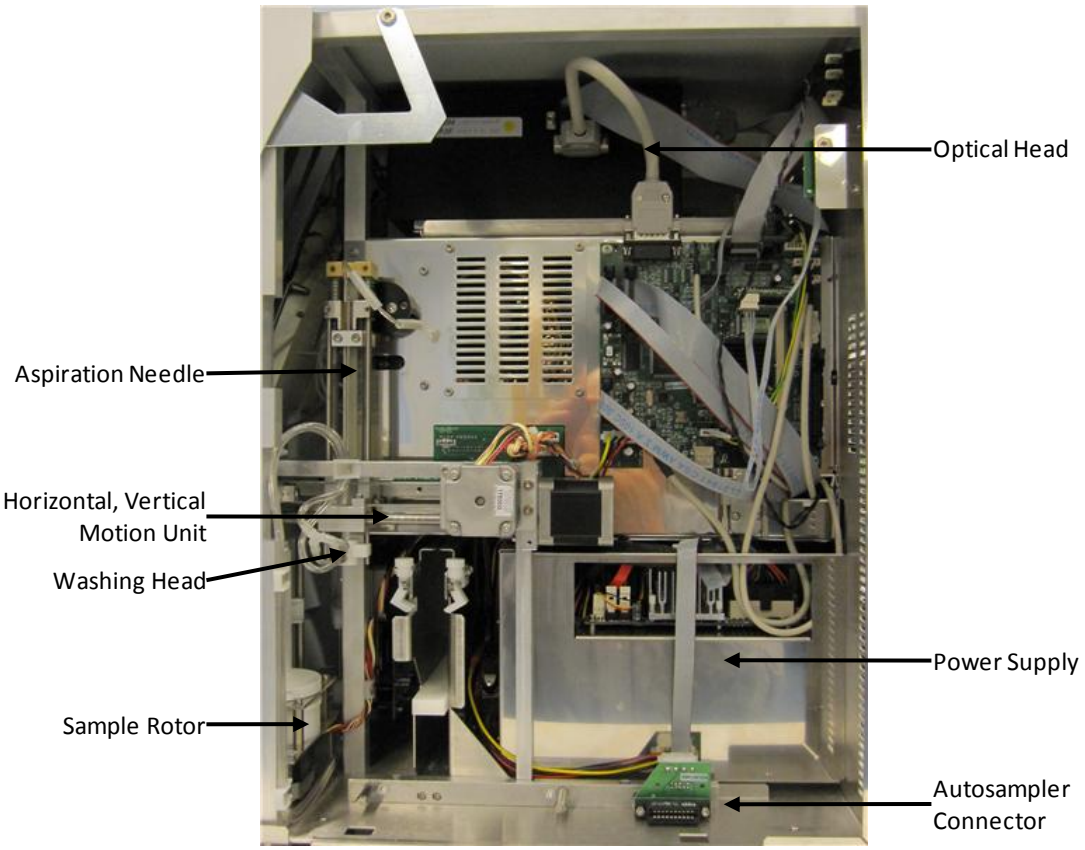


Figure 13. Left Side Assembly

- Aspirating needle aspirates a blood sample from the sample tube.
- Horizontal, vertical motion unit positions the aspiration needle.
- Washing head cleans the aspiration needle to prepare for the next sample.
- Sample rotor holds the sample tube for single tube manual presentation.
- Autosampler connector is the power and control connector of the optional Autosampler.
- Optical head contains the laser source, optical detectors and auto alignment mechanism for the optical measurement.

4.3.4 Front Assembly

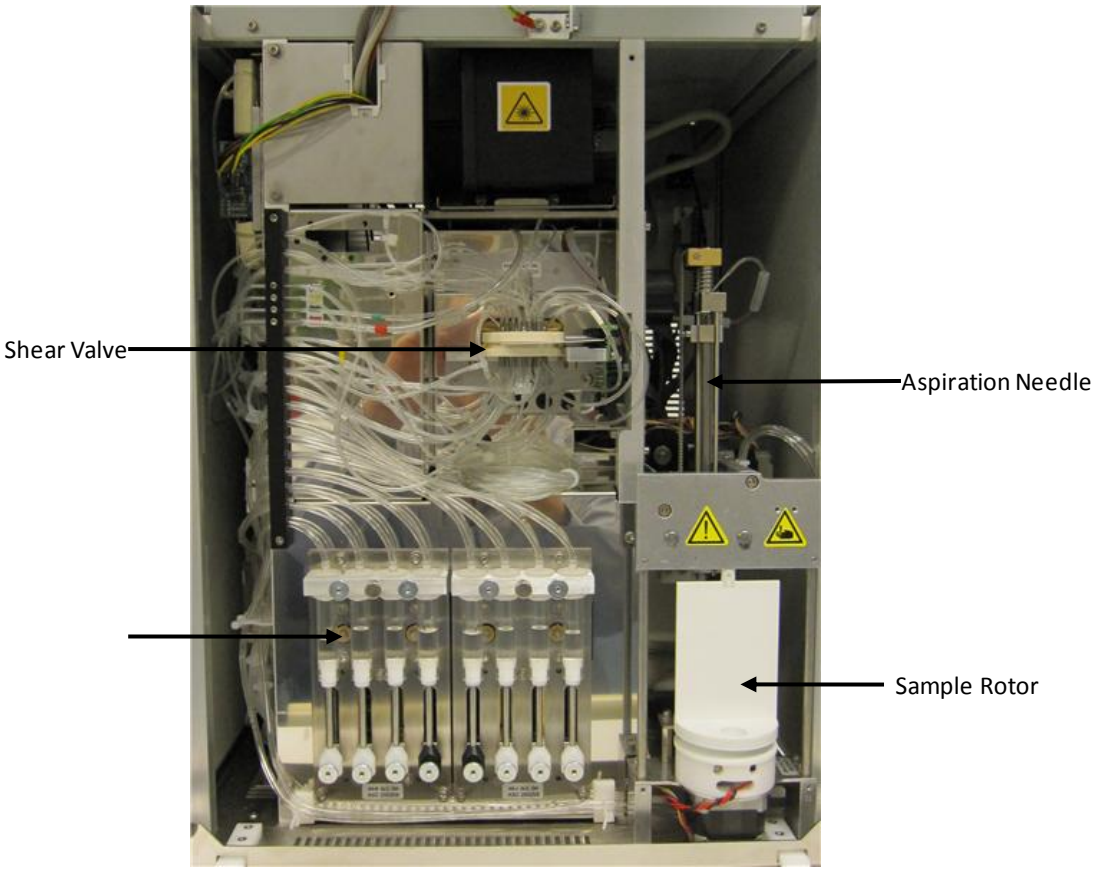


Figure 14. Front Assembly Behind the Front Panel

- Syringe pumps control the volume and flow rate of reagents through the pneumatic components.
- Shear valve is an integrated multi functional valve for segmenting precise volumes of blood.

5 User Interface

The user interface of the 'Hemolyzer 5' analyzer is designed to be intuitive and easy to use, and provide access to all user level functions. You can interact with the 'Hemolyzer 5' by using only the touch screen and the virtual on-screen keypad, or by using an external keyboard and mouse (PS2 or USB). The Start button is considered an important part of the user interface, allowing one-hand, one-touch processing of sample tubes.

5.1 Using the Touch Screen

The touch screen is a pressure sensitive overlay on the screen of the 'Hemolyzer 5'. It allows selection of menu items and pressing of buttons by gently pressing or tapping the surface over the selected item. This method is called 'tapping'. The touch-screen device used in the 'Hemolyzer 5' analyzer is selected for reliability, endurance and compatibility with the medical laboratory environment. Simple operations are supported, but multi-touch "gestures" or multiple tapping are not supported.

The touchable items on the 'Hemolyzer 5' user interface are designed to be large enough to tap with finger. The use of a tapping tool may be useful if the operator has larger or thicker fingers, or when wearing oversize gloves. A tapping tool can be pencil eraser or a specially designed stylus available at computer or consumer electronics stores.

Do not use sharp or heavy objects to operate the touch screen. The surface material is moderately resistant to liquids. Avoid touching the screen with wet fingers, or allow liquids to come in contact with the screen or the surrounding area.

If you find that the 'Hemolyzer 5' touch screen responds in a different area than the one you are tapping, then please perform a touch screen calibration procedure before calling for service or support. See chapter 15.1.5 for more details on touch screen calibration and other maintenance procedures.

5.2 Using the 'Start' Button

The 'Start' button is a physical button on the front cover of the 'Hemolyzer 5'. It has the following functions:

- Start a single tube, closed or open vial measurement using the sample rotor by pressing the Start button.
- Provide color-coded feedback about the status of the measurement system.
- Green means that the 'Hemolyzer 5' is ready to start a new measurement.
- Red means that the system is busy running a measurement or a procedure.
- Orange color means that the analyzer is in standby mode.

5.3 Using an External Mouse

An external mouse can be used to perform the same functions as the touch screen. Navigate the mouse pointer over the desired item and click the left mouse button instead of tapping the touch-screen to activate the function. This procedure is referenced as clicking (click) an item. Touch screen operation continues to be available even if an external mouse is connected to the 'Hemolyzer 5' analyzer.

It is possible to move the mouse pointer to a place on the screen where it isn't viewable. Move the mouse pointer up or to the left to make it visible again.

5.4 Using an External Keyboard

An external keyboard provides the same data entry features as the on-screen virtual keypad presented by the touch screen user interface with faster typing.

The "Settings/Customize/On screen keyboard active" check-box allows you to choose whether the on-screen virtual keypad is presented or not when data entry is required (name, sample ID, target value etc.). If the check box is left unchecked, then the on-screen virtual keypads are not presented and an external keyboard is required for data entry. If the check box remains checked, the external keyboard can still be used by pressing the 'ESC' key on the external keyboard to dismiss the on-screen virtual keyboard and complete the data entry using the external keyboard.

5.5 Using the On-Screen Virtual Keypads

There are three types of virtual on-screen keypads:

- Alpha-numeric with shift and symbol options
- Numeric only
- Date

The particular virtual on-screen keypad presented is tailored to the data entry required. If only numeric values are accepted than a numeric-only keypad is presented. For selection of dates, a date keypad is presented.

The touch-pad of the 'Hemolyzer 5' handles single taps only. The Shift and Symbol keys are 'sticky' on the virtual on-screen keypads like the 'caps-lock' on a PC key-board. Click/tap on the appropriate buttons to type in the required value. Complete the operation by clicking/tapping the 'Done' button. The 'Symbols' button presents special characters such as the question mark or ampersand.

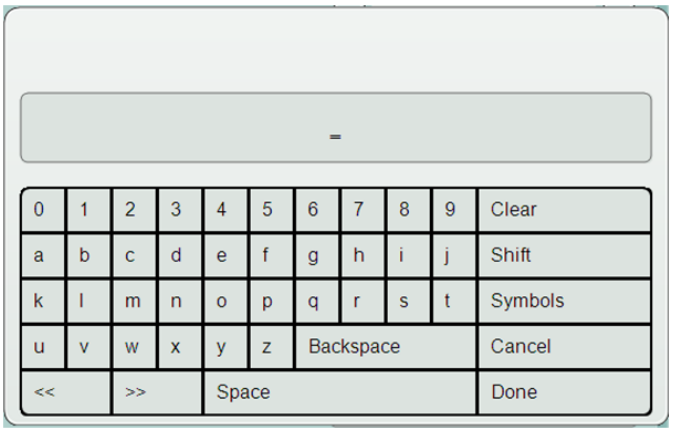


Figure 15. Alphanumeric Virtual On-Screen Keypad

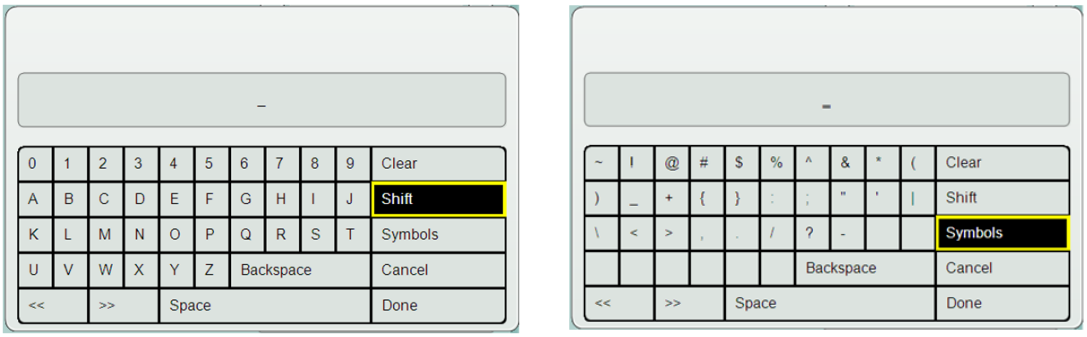

0 1 2 3 4 5 6 7 8 9 Clear
A B C D E F G H I J Shift
K L M N O P Q R S T Symbols
U V W X Y Z Backspace Cancel
<< >> Space Done
~ ! @ # $ % ^ & * (Clear
) _ + { } : ; " ' | Shift
\ < > , . / ? - Symbols
Backspace Cancel
<< >> Space Done

Figure 16. 'Sticky' Shift and Symbol Buttons

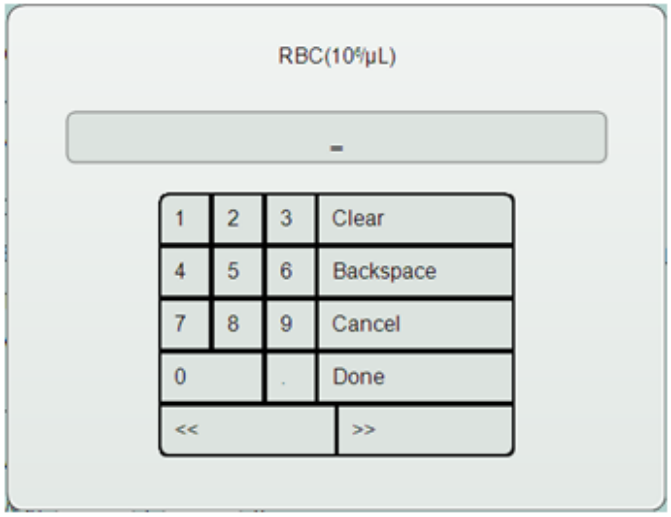


Figure 17. Numeric Virtual On-screen Keypad

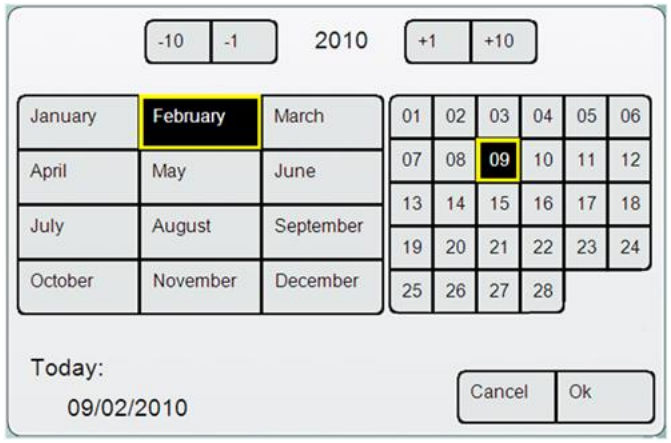


Figure 18. Date Virtual On-Screen Keypad

5.6 Using the Graphical User Interface

The graphical user interface (GUI) of the 'Hemolyzer 5' is divided into three main sections. Refer to Figure 19 to see these sections:

1. Quick links to main functions (top section)
2. Interactive display area (middle section)
3. Status display (bottom section)

The main menu shown below is displayed in the interactive display area when the 'Hemolyzer 5' analyzer is initially powered up.

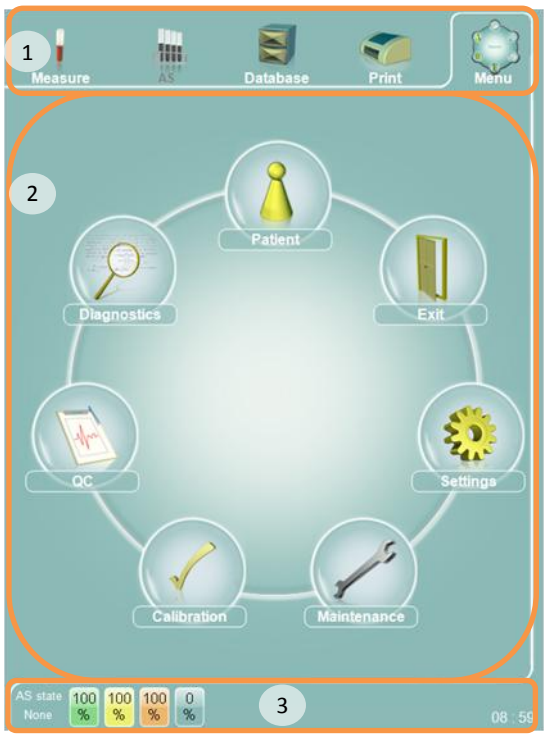


Figure 19. Graphical User Interface Sections

5.6.1 Quick Links

The upper part of the GUI is always visible during all operations and presents several quick link buttons. Selecting one of the quick link buttons determines what is displayed in the interactive display area. The selected button is framed on three sides for clear visual feedback. The quick link for Autosampler functions is enabled only if the optional Autosampler is connected.

5.6.2 The Interactive Display Area

The middle section is used to display the main menu, functions, information, results, and all the panels that contain information about the active mode.

5.6.3 The Status Display

The bottom section is called the Status display, and presents the user with the following:

- Status of the Autosampler unit
- The state of the reagent and waste containers
- Error/ warning icons
- Status of the pneumatic system (standby, manual measure, rinse, clean)
- Progress of the active operation
- Time
- Printer status

Clicking or tapping on an error or warning icon navigates directly to the relevant menu where the problem can be addressed, or provides the user with information on how to resolve the problem.

Figure 20. The Status Display

5.6.4 Entering Information

The 'Hemolyzer 5' sometimes requires the operator to enter information such as sample ID or patient data. In order to enter information into a data field simply tap or click on it. The data field will change color to yellow indicating that data entry is active for that field. Information can be entered using the virtual on-screen keypad or with an optional external keyboard.

5.7 The Menu System

The graphical user interface of the 'Hemolyzer 5' analyzer has primary functions that are accessible directly by means of icons or controls that are always available to the operator. The 'Hemolyzer 5' analyzer also has secondary functions that are available via two or more taps or clicks through the menu structure, or menu tree.

5.7.1 Primary Menu Items

The following menu items or functions are directly accessible:

- Start a manual single tube measurement
- Start an automated measurement
- Access the database
- Initiate printing
- Access the main menu
- Access the control panel of the Autosampler (opens with double click or tap)
- Access the time adjustment panel (opens with double click/tap)
- Access the warnings panel (only visible if an error or warning was reported)

5.7.2 Starting a Manual Single Tube Measurement

Tapping or clicking on the 'Measure' icon with the single sample tube graphic allows access to the following functions:

- Initiate a primary blank measurement
- Make adjustments and settings about the manual measurement:
    - Enter the Sample ID (unique or auto-increment)
    - Select the associated patient
    - Select the sample type or patient mode
- Start a manual measurement
- View the measurements results in detail:
    - View the measured parameters
    - View the calculated parameters
    - View parameters that are out of the normal range
    - View error, warning, or clinical flags

See section 7.4.1 for more information about manual measurements.

5.7.3 Start Automated Measurements

Tapping or clicking the 'AS' icon with the multiple sample tube graphic allows access to the following functions:

- Initiate automated measurements in one of three modes:
  - Full scan mode
  - Free list mode
  - Selected samples mode
- Define sample parameters (the parameter list depends which one of the three sample modes are selected)
- Monitor the progress of the automated measurements
- View the details completed measurements

See section 7.4.2 for more information about automated measurements.

5.7.4 Access the Database

Tapping or clicking the 'Database' icon with the file cabinet graphic allows access to the following functions:

- Select completed and measurement stored as database records
- Export database records for storage or import results for viewing
- Delete database records
- Send database records to the LIS
- Review the details of selected measurements

See section 9 for more information about accessing and using the 'Hemolyzer 5' database.

5.7.5 Initiate Printing

Tapping or clicking the 'Print' icon with the printer graphic will print the active panel or measurement result according to the printer settings.

See section 13.6 for more information about printing on the 'Hemolyzer 5' analyzer.

5.7.6 Main Menu

Tapping or clicking the 'Menu' icon with the main menu graphic displays and allows access to the main menu. The main menu is automatically displayed when the 'Hemolyzer 5' analyzer is started up. The main menu icons are arranged in an intuitive and attractive circular design.

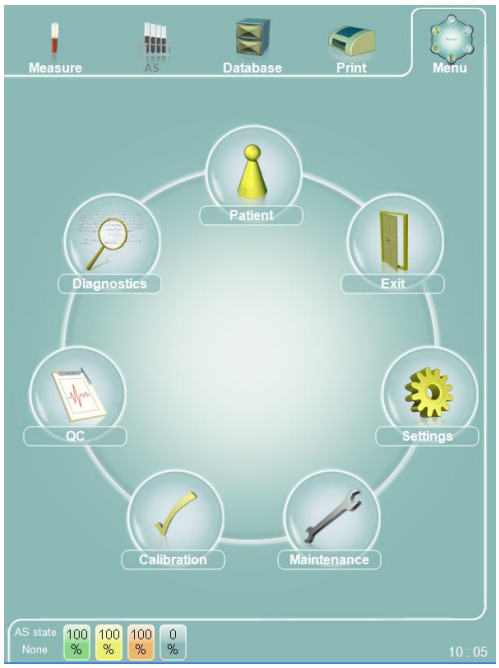


Figure 21. 'Hemolyzer 5' Main Menu

5.7.7 Autosampler Control Panel

If you have an optional Autosampler installed, the Autosampler control panel can be opened by double clicking/tapping the Autosampler status on the left side of the status display on the bottom of the screen. The Autosampler control panel allows you to see of the Autosampler is operational and perform an Autosampler initialization.

See section 7.4.2.5 for more information about the Autosampler control panel.

5.7.8 Adjust the Time and Date

Double click/tap the time display on the right side of the status display on the bottom of the screen to bring up a panel for adjusting the stored time and date of the 'Hemolyzer 5' analyzer. See section 0 for more information about time and date adjustment.

5.7.9 Open the Warning Panel

If an error or warning is currently active, an exclamation point icon appears on the status display. Click the icon to review the active error or warning and jump to the appropriate menu where the error or warning can be addressed (such as reagent replacement).

5.7.10 Menu tree

The following is a listing of the 'Hemolyzer 5' analyzer main menu tree:

Patient
New: Add a new patient
Edit: Modify an individual patient's information
Details: View an individual patient's information
See section 12 for more information about patient data
Exit
Cancel: Cancels shutdown of the 'Hemolyzer 5' analyzer
Prepare for shipment: Performs an extensive drain procedure of the 'Hemolyzer 5' pneumatic system in preparation for shipment or an extended period of inactivity

Log off: Logs off the current user session
Shutdown: Prepares the ‘Hemolyzer 5’ for a complete shutdown
See section 6.3 to learn how to power down the ‘Hemolyzer 5’ analyzer correctly
Settings
Customize
Language: Change the active language
Limit Style: View parameter normal range status in numerical or graphical format
Sound Volume: Change the volume of the ‘Hemolyzer 5’ built-in speaker
On screen keyboard active: Turn off on-screen virtual keypads for use with an optional external keyboard
Patient’s displayed data: Patient identifier visible in the database display
Laboratory: Eight lines of text of lab information be displayed on each printed page
External devices
Sending port baud rate: Select transmission rate for serial LIS
Automatic LIS: Select whether to automatically transmit results each time a sample is processed
LIS: Select Ethernet LIS connection
IP: IP address of Ethernet-based LIS host computer listening port
Port: Port number of Ethernet-based LIS host computer listening port
Bidirectional LIS: Selects whether Autosampler information downloads are allowed
System
Waste container volume: Selects a 10L, 20L, or no waste container (direct to drain)
Database display limit: Selects all or only last month of database record display
Use only Sarstedt-Monovette tub from sample rotor: Change sampling adjustments to accommodate Sarstedt Monovette tubes
Standby time: Time period of inactivity before the ‘Hemolyzer 5’ automatically enters standby
Offline rinsing frequency: Time period of inactivity before the ‘Hemolyzer 5’ performs an offline rinse to keep the pneumatic system in peak operating condition
Screen saver – Time period of inactivity before screen saver takes effect
Special flags(G, A, B): Select whether G, A, and B flags are displayed
Units
HGB unit: Selects the units for HGB and HGB-derived or calculated parameters
Count unit: Selects the units for WBC, RBC, and PLT and derived or calculated parameters
Printer
Printer: Selects which printer to print to
Printer status: Display the currently selected printer status
Color printing: Selects whether to print in color
Double sided printing: Selects whether to print multi-page printouts on both sides of a page
Items in queue: Number of items in the printer queue
Cancel all jobs: Cancels all items in the selected printer’s queue
Printout format: Allows selection of printout format (normal or wide parameter names) see section 13.6 for details
Automatic print: Selects whether to print for every new sample processed
Logo visible: Selects whether to print or omit graphical logo to printout
Refresh printers list: Refreshes the list of displayed printers
Profile limits: Enter normal ranges for various profile limits
User: Add and manage users of the ‘Hemolyzer 5’ analyzer
See section 13 for more information about ‘Hemolyzer 5’ analyzer settings
Maintenance
Clean: Perform extended cleaning of various pneumatic components
Internal reagent reservoir: Drain one or all internal reagent reservoirs
Empty chamber: Empty RBC, WBC, and mix chambers
Prime: Prime one or all reagent reservoirs
Fill: Fills the fluidic components of the system with reagents
Touchscreen: Calibrate the touchscreen location for taps and button presses
See section 15 for more information about ‘Hemolyzer 5’ maintenance procedures
Calibration

Calibration: Use a calibrator material to calibrate the system
Calibration mode: Select type of calibration procedure to run
Calibration type: Select human blood or calibrator material
Target values: Enter the target ranges for each calibrated parameter
Cancel: Cancels a calibration procedure
Next: Initiates processing of calibration run
View Calibrations: View, delete previous calibrations
See section 10 for more information about 'Hemolyzer 5' calibration
QC
QC Measure: Initiate processing of a control sample
QC Reference select: Select which stored QC reference this measurement belongs to
Set QC Reference: Create a new stored QC reference
View QC references: Browse stored QC references
View QC data: Browse individual QC sample measurements
View QC diagrams: View Levy-Jennings diagrams of QC data
See section 11 for more information about quality control on the 'Hemolyzer 5' analyzer
Diagnostics
Selftest
Load last selftest: Loads the results of the last selftest
Start electronic: Starts the electronic tests
Start both: Starts both electronic and pneumatic tests
Log: Review and obtain additional details about events in the system log
Reagent status: Reset levels for individual reagents and waste (or all) for reagent replacement
Statistics: Provides operating statistics such as cycle counts, errors, etc.
Information: Provides version information for all software items in the 'Hemolyzer 5' analyzer

Table 7. 'Hemolyzer 5' Analyzer Menu Tree

5.7.11 Safety Access Codes

Some functions require password protected confirmation. For example, deleting a record from the database requires entry of a password.

The security password for deleting database entries is: **555**.

6 Start Up and Shut Down the 'Hemolyzer 5'

6.1 Start Up and Shut Down Overview

The 'Hemolyzer 5' is an advanced instrument with computer and pneumatic subsystems that need to be properly started up and shut down for continuing reliable performance. Not following proper startup and shutdown procedures may lead to increased maintenance and unnecessary service calls.

The 'Hemolyzer 5' analyzer start up sequence requires four steps:

- Power up the electrical system.
- Start up the internal user interface computer and log in if the multi-user mode is activated.
- Start up the pneumatic system components.
- Perform and accept an initial 'blank' measurement.

A normal shut down of the 'Hemolyzer 5' analyzer has the reverse steps:

- Clean and empty the pneumatic system components.
- Log off (multi-user mode is activated) and properly shut down the internal user interface computer.
- Power down the electrical subsystem.

The 'Hemolyzer 5' analyzer also has a 'prepare for shipment' shut down option that performs an extended cleaning and emptying of the pneumatic components. This option can be used to prepare the 'Hemolyzer 5' analyzer for an extended period of inactivity or for shipping to a new location.

There are also emergency shutdown procedures in case of emergency.

6.2 Starting Up the 'Hemolyzer 5' Analyzer

6.2.1 Visual Inspection

Perform a visual inspection of the 'Hemolyzer 5' analyzer before starting up. This is particularly important if the 'Hemolyzer 5' is operated by multiple operators.

- Check the reagent tubes by gently pulling on them to make sure that connections are not loose.
- Open the front cover and ensure that there is no leakage around the shear valve or the syringe pumps.
- Check for salt stains around the reagent tubing and the reagent containers.
- Check that the power cord is plugged in both into the back panel of the 'Hemolyzer 5' analyzer and to the wall outlet.
- Empty the waste container. After start up reset the waste level in the "Main menu/ Diagnostics/Reagent status panel".

6.2.2 Power Up the 'Hemolyzer 5' Analyzer

To power up the 'Hemolyzer 5' analyzer, perform the following steps:

- Turn on the main power switch (small switch) on the rear panel of the 'Hemolyzer 5' analyzer located near the power connection to the 'up' position labeled '1' to power on the electrical system of the 'Hemolyzer 5' analyzer.

- If the optional Autosampler is installed, turn the power switch on the right side of the Autosampler to the ‘on’ position labeled ‘1’ to power on the electrical system of the Autosampler.
- Turn on printers or any peripherals that have their own power switches.

The electrical system of the ‘Hemolyzer 5’ analyzer can remain powered up indefinitely. Please follow local regulations or laboratory procedures when deciding whether to fully power down the ‘Hemolyzer 5’ analyzer after work hours.

6.2.3 Start Up the User Interface

To start up the internal user interface computer of the ‘Hemolyzer 5’ analyzer, flip the standby switch near the top of the rear panel of the ‘Hemolyzer 5’ analyzer to the ‘up’ position. The standby switch springs back to the ‘down’ position after activation.

The following sequence of events takes place after enabling the standby switch:

- The internal computer starts up displaying the ‘EPIA’ logo in a rotated way.
- The embedded Windows® XP® operating system starts up. As the display initializes the screen changes color.
- The ‘Hemolyzer 5’ application software starts up displaying the ‘Hemolyzer 5’ logo screen. Individual component start up status is displayed in the bottom right corner of the logo.
- If the multi-user option is enabled then a user ID and password is required.
- The ‘Hemolyzer 5’ main menu is displayed.

Figure 22. Start Up Logo Screen

At this point, the ‘Hemolyzer 5’ analyzer user interface is ready to use, but the analyzer is not yet ready to measure samples. This requires initialization of the ‘Hemolyzer 5’ pneumatic system. The following functions are available at this time:

- Use the patient database to add and modify entries.
- Review, archive, send to LIS and print existing measurement records.
- Review calibration and QC results and history.
- Change settings.

6.2.4 User Login

If the multi-user feature is activated, a user must be logged in before the user interface of the ‘Hemolyzer 5’ can be accessed. You can log in on two different ways:

- Enter the user ID and password assigned to your account.
- Create a new user account.

The multi-user feature of the ‘Hemolyzer 5’ analyzer tracks which user is logged on when important activities are performed such as sample or QC measurements or

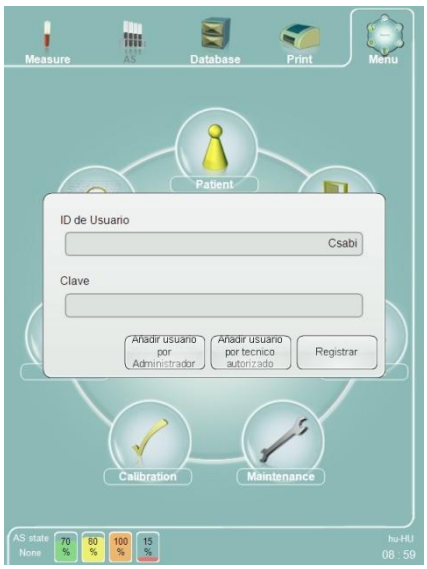


Figure 23. ‘Hemolyzer 5’ User Login Screen

calibration. The multi-user feature allows full access to administrator users while restricting regular users from actions that change the way the 'Hemolyzer 5' analyzer operates, such as changing calibration settings.

See section 13.7 for details about user management.

6.2.5 Pneumatic System Start and Blank Measurement

Before measuring any blood or control samples, the pneumatic system components of the 'Hemolyzer 5' analyzer need to be initialized and a blank measurement run and accepted. To start the pneumatic system and run a blank measurement, click or tap the 'Measure' icon with the single test tube graphic on the top left corner of the screen. The following sequence takes place:

- The color of the 'Start' button changes to red.
- The reagents are primed.
- The measuring system is flushed.
- The sample-door, syringe, needle x/y movement, and shear valve motors are activated and tested.
- The vacuum system is activated, and pump sensors and vacuum leakage is tested.
- A blank measurement is initiated automatically.
- An empty result screen is displayed.
- The blank measurement is performed.
- The results of the blank measurement are displayed.

The results of a blank measurement must be accepted before blood or control samples can be processed. If the results from the first blank measurement are not acceptable, it does not necessarily mean that something is wrong about your 'Hemolyzer 5' analyzer. Please consider the following:

- Blood proteins or other particles can accumulate in the pneumatic tubing or components.
- Although the reagents contain antimicrobial agents, some microbial growth may still be present.
- An extended period of inactivity without performing a 'prepare for shipment' procedure may result in salt crystal development in the pneumatic components.

Running additional blank measurements will usually bring the blank measurements down to an acceptable level. Blank measurements will be flagged if they exceed the following thresholds:

- WBC ≥ 0.5 * 10^3 cells/µL
- RBC ≥ 0.05 * 10^6 cells/µL
- PLT ≥ 15 * 10^3 cells/µL
- HGB ≥ 100 g/dL

If the 'Hemolyzer 5' was not in use for an extended period of time, the start up of the pneumatic system components can take significantly longer and require more blank measurements. To prevent these problems, use the 'prepare for shipment' process when the 'Hemolyzer 5' analyzer will be inactive for an extended time.

6.3 Exiting the 'Hemolyzer 5' Analyzer

After you have completed lab operations and you are ready to exit the 'Hemolyzer 5' analyzer, you can:

- Log off
- Shut down the ‘Hemolyzer 5’
- Power off the ‘Hemolyzer 5’
- Prepare the Hemolyzer 5’ for shipment

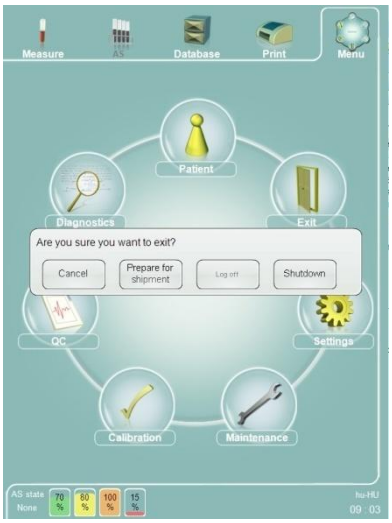


Figure 24. ‘Hemolyzer 5’ Exit

Click or tap the Exit icon on the main menu to access various exit options. Click or tap the ‘Cancel’ button to return to normal operation.

6.3.1 Log Off

Clicking or tapping the Exit icon on the main menu brings up the ‘Shutting down Analyzer’ panel. Select ‘Log off’ to end the active user session.

Figure 25. Log Off

After the current user is logged off the login panel is displayed.

6.3.2 Shut Down

The shutdown procedure must be used to maintain the reliable operation of the instrument. To properly shut down the ‘Hemolyzer 5’ analyzer, click or tap the Exit icon on the main menu and select ‘Shutdown.’

Figure 26. Shut Down

The shutdown procedure performs two key functions:

- If the pneumatic system components of the ‘Hemolyzer 5’ analyzer were initialized, a shut down procedure is performed that rinses the pneumatic components. This prepares the ‘Hemolyzer 5’ analyzer for shorter periods of inactivity such as overnight or over a weekend.
- The ‘Hemolyzer 5’ operating software and the Windows® XP® Embedded operating system are shut down. The analyzer saves all settings, closes the file system and database, and automatically shuts down the internal user interface computer.

The ‘Hemolyzer 5’ analyzer may ask to perform a cleaning cycle based on the analyzer’s usage patterns and the state of the pneumatic components. If this occurs, the ‘Hemolyzer 5’ analyzer will request that a tube with cleaning reagent be introduced at the sample rotor. The cleaning procedure may take a few minutes. Do not turn off the analyzer until it indicates that it is safe to do so.

6.3.3 Prepare for Shipment

If the 'Hemolyzer 5' analyzer is not used for a significant period of time or is being transported to a new location then the 'prepare for shipment' procedure should be performed instead the regular shutdown procedure. Click or tap the 'Exit' icon on the main menu, then select the 'Prepare for shipment' button.

Figure 27. Prepare for Shipment

⚠	If the 'Hemolyzer 5' is powered off without a proper shutdown or prepare for shipment procedure, the following may occur: • The pneumatic components may lock in an undefined state. The next startup and pneumatic initialization may take longer with increased reagent consumption. • The 'Hemolyzer 5' application software and/or the Windows® XP® Embedded operating system can suffer damage or data loss. • The 'Hemolyzer 5' analyzer may have to be restarted by a service engineer after an improper shut down or power off sequence.

The 'Prepare for Shipment' procedure should be used for following reasons:

- The reagents may spill out if the 'Hemolyzer 5' is tilted, potentially causing electrical short circuit or corrosion.
- Reagents can flow out of the 'Hemolyzer 5' if the reagent intakes are disconnected.
- Evaporation may cause reagents left in the pneumatic components in the 'Hemolyzer 5' analyzer to become concentrated and form crystals that increase blank results, damage pneumatic components, and may require a service engineer to restore proper operation.
- Microbial growth may occur if reagents are left in an inactive analyzer for extended time periods, causing high blank results and may require a service engineer to restore proper operation.

- Accidental storage at very low temperatures may cause freezing that damages the pneumatic components.

It is strongly recommended that the 'Prepare for shipment' procedure be used if the analyzer will be inactive for more than five days. Higher temperature or lower humidity decreases the period of time the 'Hemolyzer 5' can be idle without performing the 'Prepare for shipment' procedure.

The analyzer will guide you through the preparing for shipment process. This process takes about 30 minutes and requires the following items:

- "Prepare for shipment" tube set included with your 'Hemolyzer 5' analyzer
- Distilled water

After initiating the 'Prepare for shipment' procedure the system will prepare itself for the draining process. Do not power off the analyzer during these steps unless the system indicates that is safe to do so.

Step 1: The analyzer will ask you to disconnect the reagents from the reagent connectors on the back panel except for the waste connection. Leave the waste container tubing connected to the analyzer. The system will drain all inner reagent buffers throughout the pneumatic system. This step takes approximately 9 minutes. Do not turn the analyzer off during this step.

Step 2: The instrument will ask you to connect distilled water to the reagent inputs.

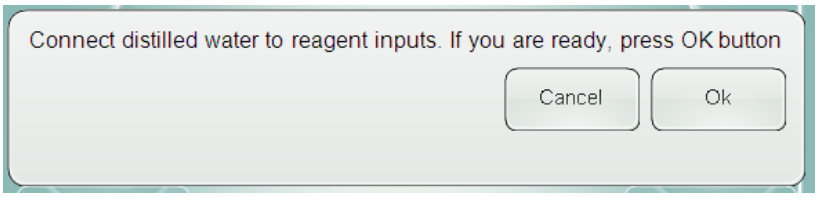


Figure 28. Connect Distilled Water Panel

Use the 'Prepare for shipment' tube set included with your 'Hemolyzer 5' analyzer to perform this step. The system will prime and fully rinse the tubing and pneumatic system with distilled water. This step takes approximately 7 minutes. Do not turn the analyzer off during this step.

Step 3: The analyzer will ask you to disconnect the 'Prepare for shipment' tube set from the reagent connectors on the back panel except for the waste connection. Leave the waste container tubing connected to the analyzer.

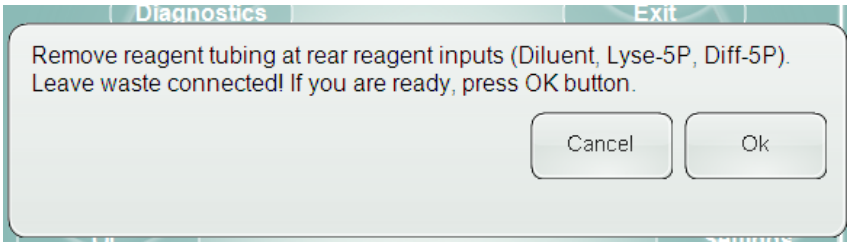

Diagnostics
Exit
Remove reagent tubing at rear reagent inputs (Diluent, Lyse-5P, Diff-5P).
Leave waste connected! If you are ready, press OK button.
Cancel
Ok

Figure 29. Remove Reagent Tubing Panel

The analyzer will drain all liquids from the instrument. This step takes approximately 10 minutes. Do not turn the analyzer off during this step. When the process is over, the system will notify you about switching off the instrument. Click or tap the 'OK' button on the notification panel and wait until the Windows® XP® Embedded exits and power off the user interface computer.

⚠	Do not turn off power of the 'Hemolyzer 5' at this stage. First click or tap the 'OK' button, then wait until the Windows® XP® Embedded operating system exits and shuts down the internal 'Hemolyzer 5' user interface computer. After the shut down process is completed, you can turn off the main power switch (small switch) on the rear panel of the 'Hemolyzer 5' analyzer near the power connection to the 'down' position labeled '0'.

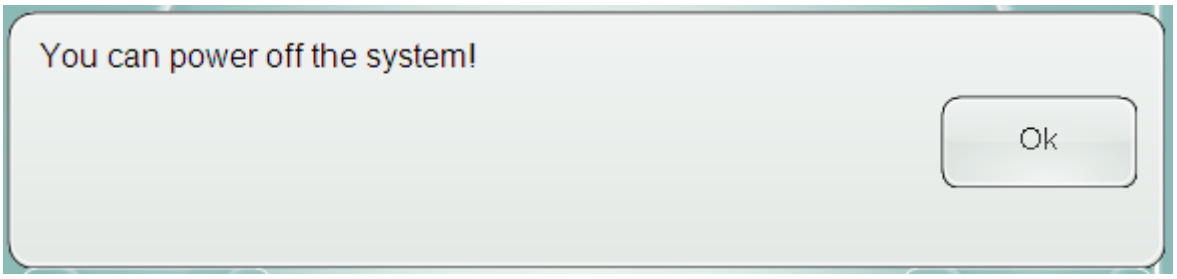


Figure 30. Shut Down Ready Panel

Step 4: Disconnect the waste container tubing from the waste reagent connector on the back panel of the 'Hemolyzer 5' analyzer.

Small droplets of distilled water may remain in the tubing after the 'Prepare for shipment' process completes. These droplets will not cause any malfunction during transportation or the next start up procedure.

6.3.4 Emergency Shut Down

⚠ The procedures described in this section can damage the 'Hemolyzer 5' analyzer or cause data loss or damage to critical system computer files. Use these procedures in case of emergency only!

6.3.4.1 Immediate Shut-Down

The immediate shut-down can be initiated by pressing the standby button near the top of the back panel of the 'Hemolyzer 5' analyzer. This is the same button which is used to start up the 'Hemolyzer 5' user interface computer. This shuts down the user interface computer without properly shutting down the pneumatic system components.

Possible side-effects:

- The pneumatic components may be left in an undefined state. The next startup and pneumatic initialization may take longer with increased reagent consumption.
- The last settings changes and measurement results are not saved.

Immediate shut down should be avoided as a routine procedure. It should only be used if loss of electrical power is imminent such as thunderstorms or if loss of uninterruptible power supply (UPS) backup power is imminent.

6.3.4.2 Immediate Switch Off

In case of immediate danger you can power off the 'Hemolyzer 5' analyzer by turning off laboratory power, or by turning off the main power switch (small switch) on the rear panel of the 'Hemolyzer 5' analyzer located near the power connection to the 'down' position labeled '0'.

6.3.5 Repackaging the 'Hemolyzer 5' Analyzer

Before repackaging your 'Hemolyzer 5' analyzer for transportation or storage, always do the following:

- Perform a 'Prepare for shipment' procedure.
- Fully power down the analyzer.
- Disconnect all reagent tubes, power cords and peripheral connections.
- Always use the original packaging materials to repackage the 'Hemolyzer 5' analyzer.

Prepare the following packaging materials were included in your original shipment:

- Mini-pallet
- Upper and lower packaging foams
- Upper and lower carton box
- Plastic bag

Place the pallet on the ground. Place the lower part of the carton box on the pallet, and place the lower packaging foam on the carton bottom.

Put the 'Hemolyzer 5' into the plastic bag, and place it into the bottom foam part. Place the top packaging foam on the analyzer, and put the top carton cover box over the package. Align the lower carton box flaps so that they fit beneath the upper box edges.

Use shipping straps to gently but firmly hold the entire package together.

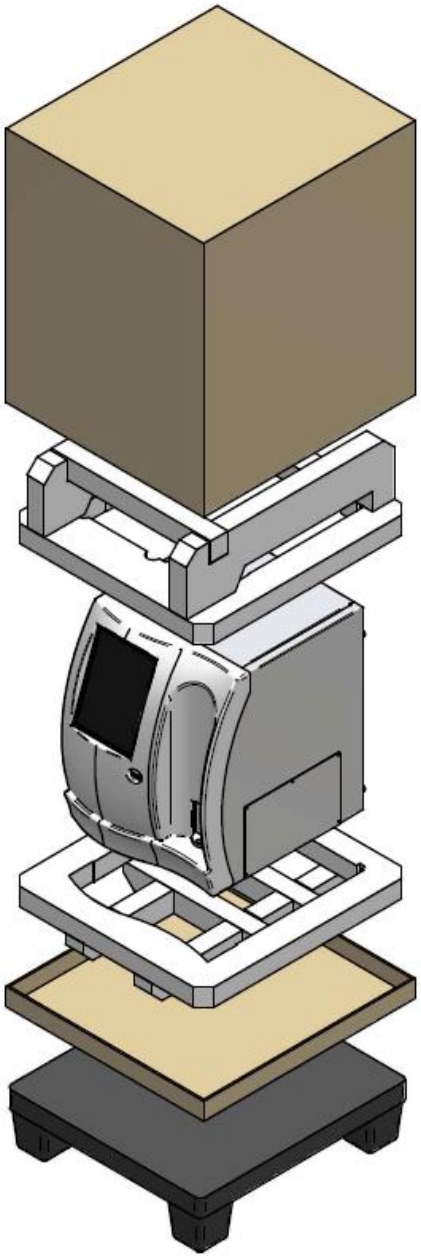


Figure 31. 'Hemolyzer 5' Analyzer Repackaging

7 Sample Measurement

7.1 Sample Types Supported by the 'Hemolyzer 5'

In this chapter you will find information about the samples usable with the 'Hemolyzer 5' instrument.

7.1.1 Supported Sample Tubes Types

The 'Hemolyzer 5' supports the following K3-EDTA, 13x75mm sample-tubes:

- Sarstedt Monovette®
- Becton Dickinson (BD) Vacutainer®
- Terumo Venosafe®

Only use sample tubes with K3-EDTA anticoagulant.

	Please note that the Sarstedt Monovette® sample tubes have a false bottom that is not the same as the bottom of the sample tube. The sampling depth on the 'Hemolyzer 5' analyzer must be changed for a Sarstedt Monovette® sample tube. To change the sampling depth for manually presented Sarstedt Monovette® tubes at the sample rotor, check the 'Use only Sarstedt Monovette tube from sample rotor' check box in the Main menu/Settings/System panel. The Autosampler automatically recognizes Sarstedt Monovette® tubes and automatically changes the sampling depth.

You may use sample tubes from other vendors if certain conditions are fulfilled. For manually presented sample tubes at the sample rotor measurement check if the new tube type:

- Is mechanically compatible (13x75 mm family)
- Can be pierced or used in open vial mode
- Can be handled by the tube centralizing mechanisms on the 'Hemolyzer 5' analyzer

It is suggested to contact your sales representative before using the new sample tube type.

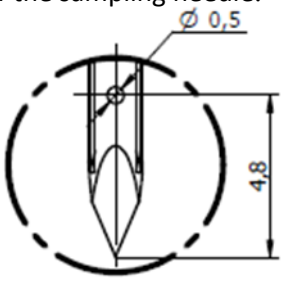
For automated sample handling with the optional Autosampler, contact your sales representative before using a new sample tube type. The Autosampler may not reliably recognize sample tube types other than the officially supported sample tubes.

Although these sample tube types are designed for multiple piercing, it is recommended to replace the cap after 3-4 piercing cycles. Small rubber bits parts can crumble into the blood and adversely affect the performance of the 'Hemolyzer 5' analyzer.

7.1.2 Sampling Depth

The 'Hemolyzer 5' is equipped with a piercing needle capable of aspirating samples from closed sample tubes. To prevent needle blockage from rubber sample tube cap material and blood particulates, the piercing needle hole is located on the side of the needle rather than at the bottom. Also, the sampling needle is given a safety clearance of two millimeters from the bottom of the tube to prevent accidental breakage of sample tubes. This means that the sampling needle cannot aspirate the last 8 millimeters (0.31 inches) of sample at the bottom of a tube. This results in sample volume that cannot be aspirated of 0.5 ml for a Beckton Dickinson Vacutainer® tube and 0.3 ml for a Sarstedt Monovette® tube.

The sampling hole is 4,8 mm (~0.19”) from the tip of the sampling needle.



On the cross-section of the piercing needle you can see the 3 grooves designed to equalize the pressure in the closed sample-tubes.

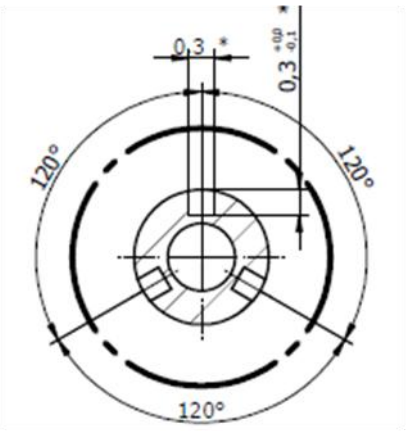


Figure 32. Sampling Needle

7.1.3 Open or Closed Sample Tubes

The ‘Hemolyzer 5’ can process both open and closed sample tubes in manual mode using the sample rotor. Manually presented sample tubes must be mixed properly before being presented to the ‘Hemolyzer 5’ analyzer.

Only closed sample tubes will be automatically processed by the optional Autosampler. Open sample tubes placed in the Autosampler will be skipped and not processed.

7.1.4 Sample Collection and Handling

Please consider the following when collecting and handling blood samples:

- The ‘Hemolyzer 5’ analyzer aspirates 110 µL of sample in both closed and open vial modes. Under the following conditions, the ‘Hemolyzer 5’ may aspirate less than 110 µL of sample, but will detect and flag any inadequate sample aspirations:
    - The sample tube does not vent properly and contains residual vacuum
    - The viscosity of the blood is very high
- The ‘Hemolyzer 5’ is unable to aspirate the last 8 mm (0.31 inches) or 0.3 to 0.5 ml of sample volume.
- Make sure that the sample tube is filled to the sample level line indicated by the tube manufacturer. The anticoagulant not only prevents the coagulation of blood, but also dilutes it. If the volume of blood is too low, than this dilution can adversely affect measurement results.
- Ensure that the blood and anticoagulant are properly mixed by inverting it at least 8 times. Do not shake the sample as this could damage blood cells.
- A minimum of 30 minutes should elapse between taking the blood sample and running it on the ‘Hemolyzer 5’ for analysis to ensure that the interaction of blood and anticoagulant has fully stabilized. Check the data sheet of the sample tube for the exact period of time.
- Use only K3-EDTA anticoagulated fresh whole blood as sample.
- Analyze blood samples within 12 hours of collection.
- It is a good practice to refrigerate (but not freeze) blood samples. Freezing causes blood to hemolyse, becoming unsuitable for hematological testing.
- Samples should be analyzed at room temperature.
- Do not deliver or store the samples at temperatures above normal body temperature.

	All samples should be handled as potentially infectious material and treated as a biohazard.

7.2 Sample Types and Modes

The 'Hemolyzer 5' analyzer is designed to process the following sample types:

- Whole human blood to determine the hematology parameters of the blood
- Quality control (QC) materials for quality control purposes
- Calibrator materials for calibration of the hematology parameters

QC samples are artificially modified human or human and animal blood samples with known parameter values. QC samples can be stored for a period of time as indicated by the manufacturer.

The 'Hemolyzer 5' analyzer works in the following modes. The sample mode must be selected before a measurement starts:

- Blank mode: No sample need be presented to run a blank. Blank mode checks that the measuring system is operating correctly and that blank measurement results are acceptable.
- Human blood mode: Choose one of five human blood modes (Human, Male, Female, Alternate 1 or Alternate 2). Each mode has a unique set of normal ranges associated with it.
- Control (QC) mode: The hematological parameters of QC materials are known prior to analysis. Controls are used to check the long term stability of the 'Hemolyzer 5' analyzer.

Calibration with a calibrator material is not one of the 'Hemolyzer 5' sample modes, but a specific procedure that can be accessed from the Calibration icon on the main menu.

7.3 Sample Identification

The following sample information items are used to uniquely identify samples:

- Sample Mode
- Measurement time: assigned automatically by the 'Hemolyzer 5' analyzer
- Result ID: unique database identifier automatically assigned by the 'Hemolyzer 5' analyzer
- Sample ID: assigned by the operator
    - The 'Hemolyzer 5' doesn't require the sample ID to be unique
    - The sample ID can submitted by:
        - Manual typing
        - Bar code reading (manual or Autosampler)
        - Auto-increment
    - The sample ID is not applicable on blank measurements
- Patient:
    - A record from the patient database connected to a measurement
    - Not applicable for blank and QC measurements
    - Can be changed by setting the name or the database identifier of the patient displayed with the measurement results
    - The 'default' patient (ID =1) patient is used if no patient is selected

7.4 Running Samples

The ‘Hemolyzer 5’ supports both manual and automatic sample presentation modes. Automatic sample presentation requires the optional Autosampler. The ‘Hemolyzer 5’ analyzer software automatically detects and initializes the Autosampler.

Before performing any measurement the ‘Hemolyzer 5’ should be:

- Powered up and started
- The pneumatic system initialized and a blank measurement performed and accepted

7.4.1 Manual Mode

To use Sarstedt Monovette® manually presented tubes at the sample rotor, check the ‘Use only Sarstedt Monovette tube from sample rotor’ check box in the Main menu/Settings/System panel.

	Always ensure the ‘Use only Sarstedt Monovette tube from sample rotor’ check box in the Main menu/Settings/System panel is checked if you are manually presenting Sarstedt Monovette® tubes in the sample rotor. Needle damage, tube damage and spilled blood may result if Sarstedt Monovette® tubes are presented and this option is not checked.

Select the ‘Measure’ quick link at the top left of the screen to initiate a manual measurement. The new measurement panel opens, giving you have the following options:

- Review the results of the previous measurement by using the ‘Last Measure’ function. This feature can be useful if you were interrupted during the measurement batch, and you want to double-check which sample is the last processed sample.
- Define the sample id of the sample to be processed by clicking or tapping on the “Sample ID” field:
  - You can type it in the Sample ID using the virtual on-screen keypad or an external keyboard.
  - You can use an external (USB) bar-code reader.
  - You can use a auto-generated sample ID.
- Activate or deactivate the automatic generation of sample IDs. If the ‘Autoincrement mode’ check box is checked, then the ‘Hemolyzer 5’ will add 1 to the last sample ID if it was fully numeric or offer ‘0’ if the last sample ID had any non-numeric characters.

Figure 34. Manual Measure Panel

- Connect a patient to the sample by clicking/ tapping on the Patient field:
  - The name of this field can be ‘Name’ or ‘ID’ depending on the ‘Main Menu Settings/ Customize/Patient’s displayed data’ setting.

- If you don't select a patient then the default patient will be used.
- As you select the patient field, the patient menu is displayed. You can select an existing patient or define a new one. See section 12 or more detail about Patients on the 'Hemolyzer 5' analyzer.

- Select the sample mode:
  - Blank: a blank measurement will be processed. This is the only option available if the pneumatic system is not initialized, or the 'Hemolyzer 5' was inactive for an extended period of time. After performing and accepting a blank measurement the other modes will be available.
  - Control: a QC sample is expected. QC measurements initiated from this menu will not be saved into the QC database, and are not part of the QC procedure. This mode is intended only as a quick system checks. See section 11 for more information about the QC process.
  - Human blood modes: Human, Male, Female, Alternate 1, and Alternate 2. Select the mode which has the appropriate normal ranges.
- Start the measurement by clicking or tapping the 'Start' button on the screen or by pressing the physical 'Start' button located on the front panel of the 'Hemolyzer 5'.

After starting the measurement the sample door rotates and takes the sample tube inside the 'Hemolyzer 5' analyzer. This is a key safety feature of the 'Hemolyzer 5' and protects the operator from the sample needle during routine operation. The Start button changes color to red to indicate that the system is busy processing the sample. The sample is aspirated inside the analyzer and returned to the operator when the sampling process is complete. As soon as the measurement results are available the result screen is displayed. See section 8 for more information about the results screen.

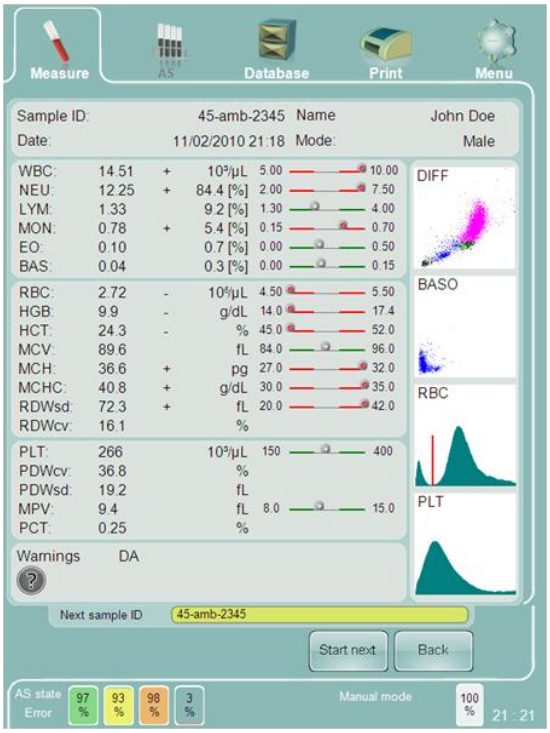


Figure 35. Result Screen

The ‘Hemolyzer 5’ analyzer will be ready to take the next sample after it has finished cleaning and preparing for the next sample. The Start button will change to green indicating it is ready to start the next sample measurement.

On the result screen you have the following options:

- You can print the results by clicking/ tapping on the ‘Print’ quick link at the top of the screen. Please note that the printing is a feature that is always available. See section 5.6.1 for more details about printing.
- Return to the measurement panel by clicking or tapping the using the ‘Back’ button.
- Run the next sample in routine mode by:
    - Editing the ‘Next sample ID’ just below the actual results
    - Accepting the auto-generated sample ID
    - Starting the next measurement by clicking/ tapping the ‘Start’ button on the screen or by pressing the physical ‘Start’ button on the front panel of the ‘Hemolyzer 5’.
    - Please note that in this mode the patient and sample mode will be carried over from the previous sample unless they are changed.

7.4.2 Automatic Mode

Only human samples in closed sample tubes can be processed in automatic mode from the Autosampler. QC samples and open tubes must be processed in manual mode.

After starting up the ‘Hemolyzer 5’, select the ‘Measure’ quick link. Process a new blank must be processed if this is the first time a new measurement panel is opened since starting up, or if an earlier blank has expired due to inactivity. An accepted blank measurement is required before starting automatic sample processing.

Open the AS panel by using the “AS” quick link at the top of the screen.

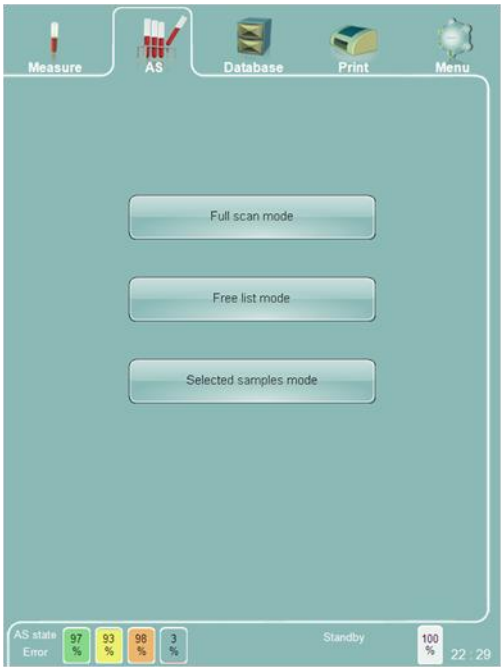


Figure 36. Autosampler Info and AS Panel

From the AS panel, you can initiate automated sample measurement in 3 modes:

- Full Scan mode:
  - The Autosampler will scan the whole sample tray
  - The same sample mode (Human, Male, Female, Alternate 1, Alternate 2) will be used for all the samples
  - The sample ID is generated from the sample tube barcode (if available)
  - It is not possible to assign a patient to automatically processed samples. The default patient will be used for all samples.
- Free List mode:
  - The samples are defined in a list.
  - The following parameters can be individually defined per sample:
    - Sample ID
    - Patient
    - Sample mode
  - The samples should be placed in the same order in the sample tray as the samples defined in the list.
  - Empty sample positions will be skipped on the sample tray.
- Selected Samples mode:
  - A sample can be defined for each position on the sample tray.
  - Only defined samples positions on the sample tray will be processed. Additional samples will be skipped and missing samples will be marked for later review.
  - The following parameters can be defined per sample:
    - Sample ID
    - Patient
    - Sample mode

Samples are automatically scanned and processed in the following order:

- Rack order starting with rack ‘A’ to rack ‘J’
  - Rack ‘A’ is the rack nearest to the front panel of the ‘Hemolyzer 5’
  - Rack ‘J’ is the rack nearest to the back panel of the ‘Hemolyzer 5’
- Sample order for each rack starting with sample ‘1’ to sample ‘10’
  - Sample ‘1’ is the sample closest to the ‘Hemolyzer 5’
  - Sample ‘10’ is the sample closest to rounded edge of the Autosampler cover
- Sample A1 is the first sample processed and sample J10 is the last.

7.4.2.1 Full Scan Mode

Full Scan mode is suitable for laboratories where:

- There are batches of samples with the same sample mode,
- Barcode labels are in use, and
- An LIS system rather than the ‘Hemolyzer 5’ is used to associate patients with sample results.

In Full Scan mode it is possible to add more samples to the batch after starting the automated measurement. As usual, an accepted blank is necessary before starting automatic sample processing.

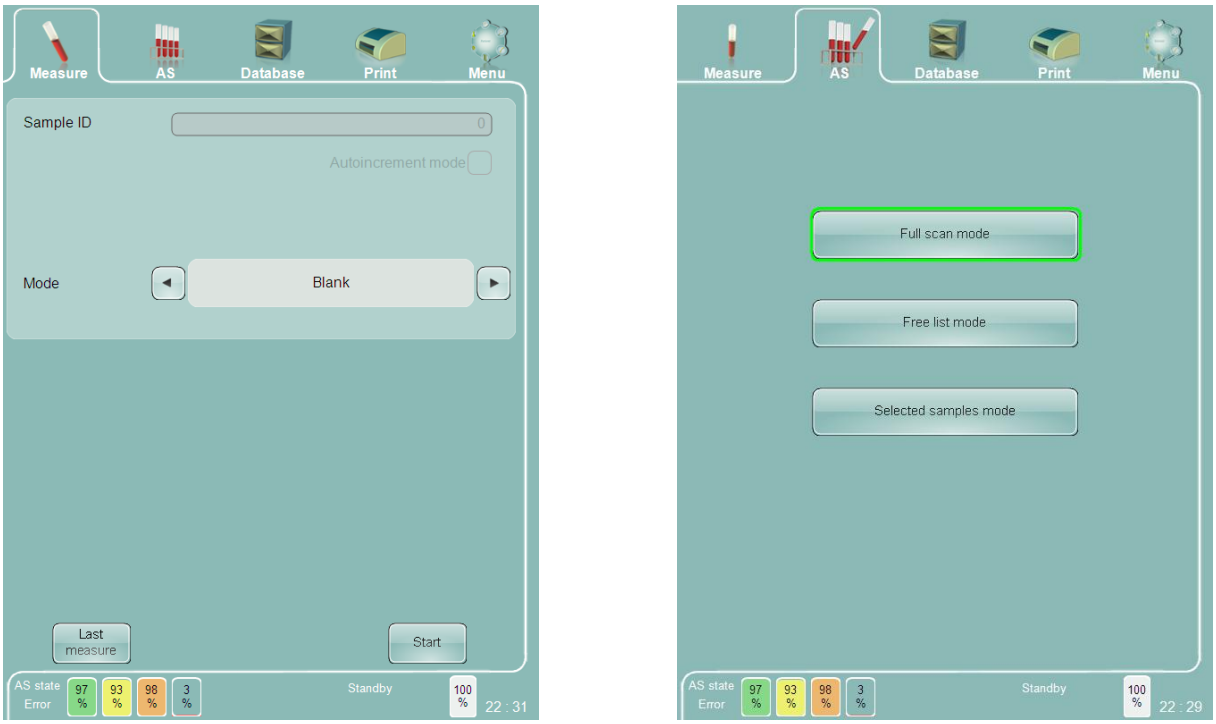


Figure 37. Full Scan Automatic Processing Mode

On the Full Scan mode panel you can:

- Return to the AS panel to select a different type of automated measurement by using the 'Back' function.
- Select a common measure mode for all samples in the tray.
- Swap between the tray and list views by using the 'View list' and 'View tray' functions.
- Start the automated measurement by clicking or tapping on the 'Start' button on the GUI.

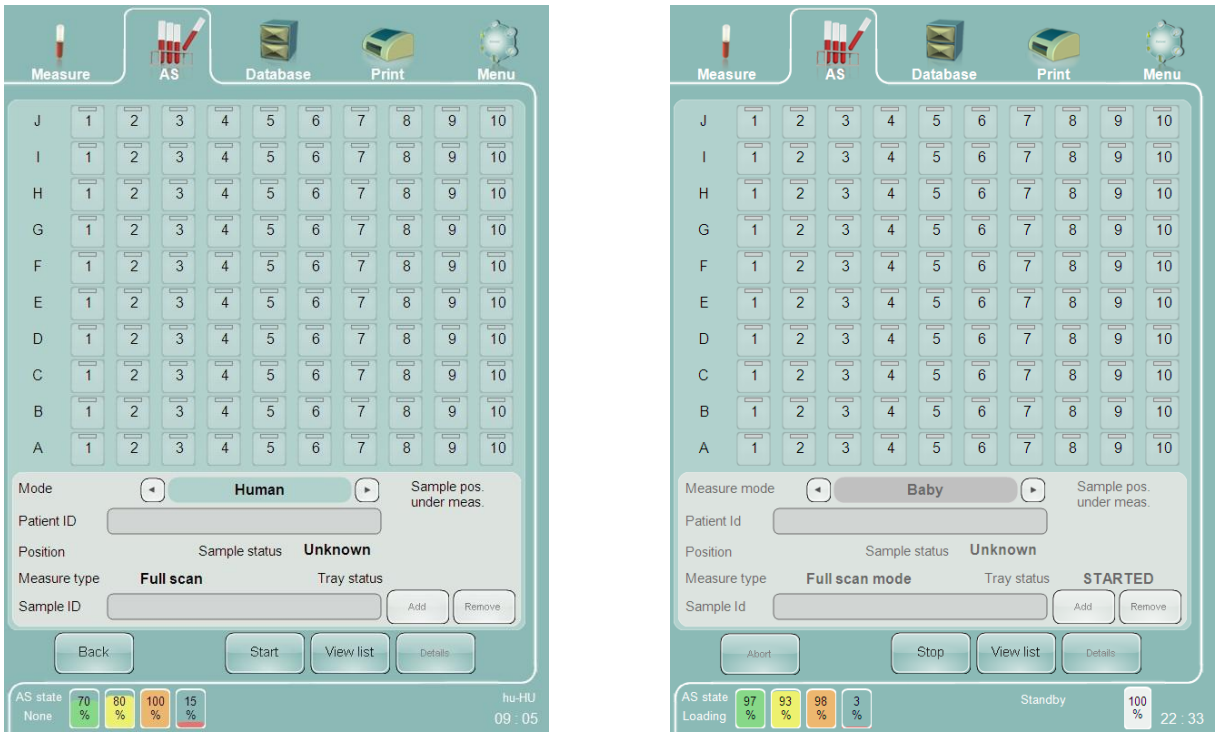


Figure 38. Full Scan Mode Tray View Progress

After starting the automated measurement in Full Scan mode, the Autosampler will scan all the sample positions on the tray. Any rows with missing racks will be skipped. The Autosampler can detect the tube type and whether the tube has a cap. Sample tubes will be skipped if it has no cap or the Autosampler cannot determine the tube type.

The Autosampler then mixes the sample tube and reads the barcode label if one is used. The sample tube is then moved to the aspiration position where the sample is aspirated and measurement is performed. The aspiration and measurement process is the same in automatic mode as in manual mode.

The sample tray progress can be followed in the tray view or the list view. The results for completed samples can be reviewed by clicking or tapping on a completed sample.

The patient ID is not editable in the Full Scan mode as it is automatically set to the default patient. The sample ID is not editable as it is read from the barcode label. If the barcode label is missing or not readable, the ‘Hemolyzer 5’ analyzer assigns a default value and allows manual entry of the sample ID.

Figure 39. Full Scan Mode Tray and List Views

The Autosampler allows the addition of sample tubes to a Full Scan process already in progress. To add more sample tubes, perform the following steps:

- Click or tap the ‘Stop’ button. The ‘Hemolyzer 5’ will prompt you to wait until the current sample is completed.
- Acknowledge the message by clicking or tapping the ‘OK’ button.
- Insert the new samples into a rack.
- Open the cover of the Autosampler.
- Place the new samples behind the last measured sample.
- Close the Autosampler cover.
- Start the automated measurement by clicking or tapping on the ‘Start’ button on the GUI or by pressing the physical Start button.

The ‘Hemolyzer 5’ analyzer keeps track of the last analyzed sample on the sample tray of the Autosampler. After restarting the full scan process the ‘Hemolyzer 5’ moves the Autosampler to the last processed position and continues scanning from there.

7.4.2.2 Free List Mode

Free List mode is suitable for laboratories where:

- The barcode labels are not used, or the bar codes are not the primary identifiers.
- Samples are arriving from multiple sources in small batches.
- In a given batch there are samples which should be measured using different modes for different normal ranges.

To start sample measurement in Free List mode, first perform and accept a blank measurement if one is needed. Click or tap the ‘AS’ quick link at the top of the screen and select ‘Free list mode’. The Free List mode only requires that samples be placed in the same sequence as in the free list. It does

not require that samples be matched to exact rack and sample positions. It is not possible to add additional samples to the batch in free list mode after automated measurement has started.

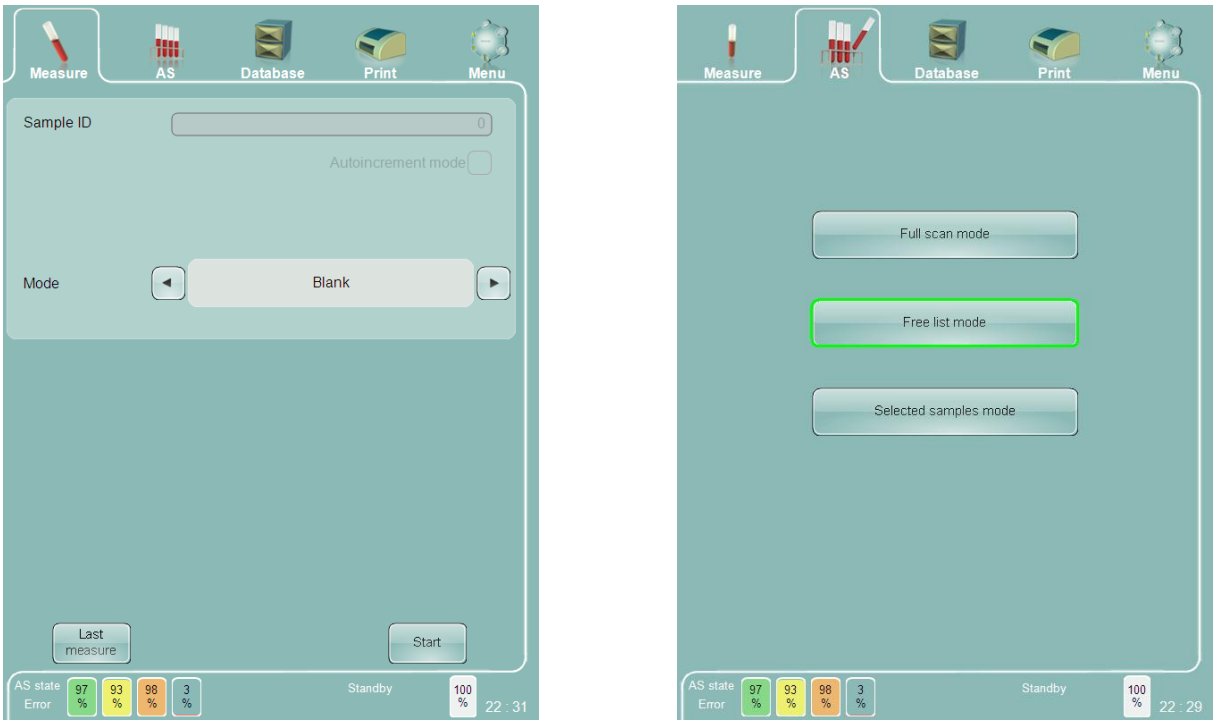


Figure 40. Free List Mode Selection

On the Free List mode panel you can:

- Return to the AS panel to select a different type of automated measurement by using the 'Back' function
- Add or remove list items
- Define the following parameters for the new list items:
    - Measure mode
    - Sample ID
    - Patient ID
- Swap between the tray and list views by using the 'View list' and 'View tray' functions
- Start the automated measurement by clicking or tapping on the 'Start' button on the GUI or by pressing the physical Start button

Figure 41 Figure 42. Preparing a Free List

As with the Full Scan mode, the Autosampler will scan all the sample positions on the tray and rows with missing racks will be skipped. The Autosampler will only process tube types it recognizes with caps attached. The automated mixing, aspiration, and analysis process is the same as the Full Scan Mode, and the progress can be followed in tray or list view.

The main difference between the Free List mode and the Full Scan mode is that the Free List mode identifies samples by matching them sequentially to the list, and comparing their measurement results to the normal range associated with the sample mode selected for that sample.

Figure 43. Free List Mode Progress: List View

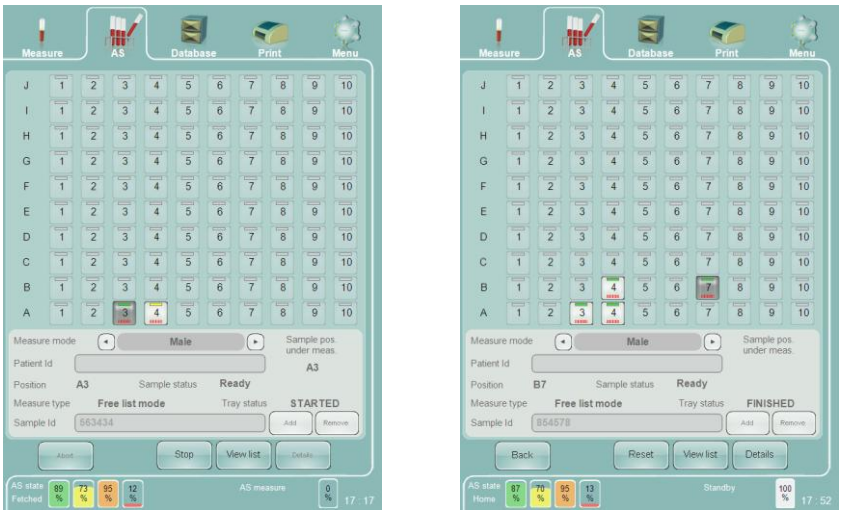


Figure 44. Free List Mode Progress: Tray View

Sample barcode labels are read and compared with the sample ID that was previously entered into the free list before starting automatic processing. If the two do not match, the barcode part of the tray view sample icon changes to red.

If the automated interrupted for any reason, it can be restarted it by clicking or tapping on the 'Start' button on the screen or by pressing the physical Start button.

7.4.2.3 Selected Samples Mode

Selected Samples mode is suitable for laboratories where:

- Barcode labels are used.
- In a given batch there are samples which should be measured using different modes for different normal ranges.
- Data security is a concern.

Selected Samples mode can also be used to rerun only certain samples in a sample tray already processed in one of the other two modes. Samples cannot be added to the sample tray once automatic processing is started in Selected Samples mode. An accepted blank measurement is required as with all sample processing.

In Selected Samples mode, the 'Hemolyzer 5' analyzer will only look for samples in the sample positions selected for analysis. All other samples in sample positions that are not selected will be ignored. If a sample position is selected for processing but contains no sample tube, the sample position will be marked for review.

On the Selected Sample mode panel you can:

- Return to the AS panel to select a different type of automated measurement by using the 'Back' function.
- Define the samples to be measured:
    - Click or tap the sample tray position icon where the selected sample is located.
    - Select the appropriate measure mode.
    - Define the sample ID.
    - Define the patient ID.

- Save the changes by clicking or tapping the ‘Add’ button.

- Remove selected samples by clicking or tapping the “Remove” button.
- Swap between the tray and list views by using the ‘View list’ and View tray’ functions.
- Start the automated measurement by clicking or tapping on the ‘Start’ button on the GUI or by pressing the physical Start button

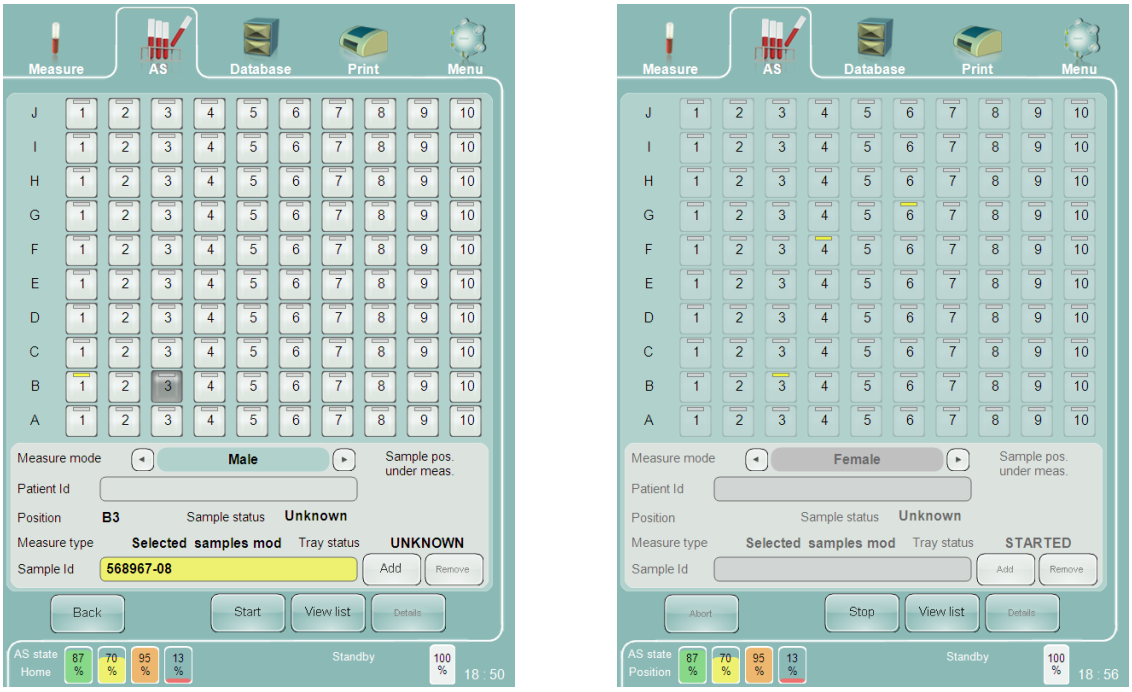


Figure 45. Selected Sample Mode Panel

7.4.2.4 Interrupting Automatic Processing for Stat Samples

If one or more stat samples need to be processed, you can interrupt automatic processing to analyze the stat sample(s) without having to wait until the entire sample tray has been processed. To interrupt automatic processing for stat specimens, perform the following steps:

- Click or tap the ‘Stop’ button. The ‘Hemolyzer 5’ will prompt you to wait until the current sample is completed.
- Acknowledge the message by clicking or tapping the ‘OK’ button.
- Place the stat sample into the sample rotor.
- As soon as the current measurement completes change to the manual measurement panel by clicking or tapping the ‘Measure’ quick-link at the upper left corner of the screen.
- Process the stat sample(s) in manual mode.
- Return to the automated measurement panel by clicking or tapping the ‘AS’ quick link;
- Restart the measurement by clicking or tapping the ‘Start’ button or by pressing the physical Start button.
- The ‘Hemolyzer 5’ will continue automated measurement from where it was interrupted.

7.4.2.5 Controlling The Autosampler

Detailed information about the Autosampler is available from the Autosampler info panel. You can also reset the Autosampler from this panel. Double click or tap the Autosampler status in the bottom left corner of the screen to view the Autosampler info panel. With this panel, you can command the

Autosampler to repeat the last command, or reset the Autosampler. You can also view Autosampler messages with detailed information about the last action or sample tube processed.

Figure 46. Control The Autosampler With Info Panel

The following is a list of messages from the Autosampler:

- Home message:
  - Response after a successful reset
  - +HOME_XX.YY (The XX.YY is the software revision number)
- VT zzzzzz XY:
  - Vacutainer® style tube detected
  - Barcode content: “zzzzzzzzzz”
  - Tray position XY
- MV zzzzzz XY:
  - Monovette® style tube detected
  - Barcode content: “zzzzzzzzzz”
  - Tray position XY
- +F : confirmation that the tube was moved from the mixing to the sampling position
- The power-on message contains the serial number of the Autosampler unit.

During the reset cycle the Autosampler moves the Autosampler components to their ‘home position’. The mixing stations moves to an upright position, the active rack moves back on to the sample tray, and the entire tray moves to its home position.

7.5 Result Display

After the analysis is completed, the result screen displays all measured parameters, flags, histograms and scatter plots. This information is automatically stored in the database, and stored result data can be retrieved at any time from the database.

Histograms and scatter plots can be zoomed for closer inspection. Click or tap the histogram or scatter plot to magnify it. Click or tap the ‘Close’ button on the upper right corner of the image to close it and return to the result display.

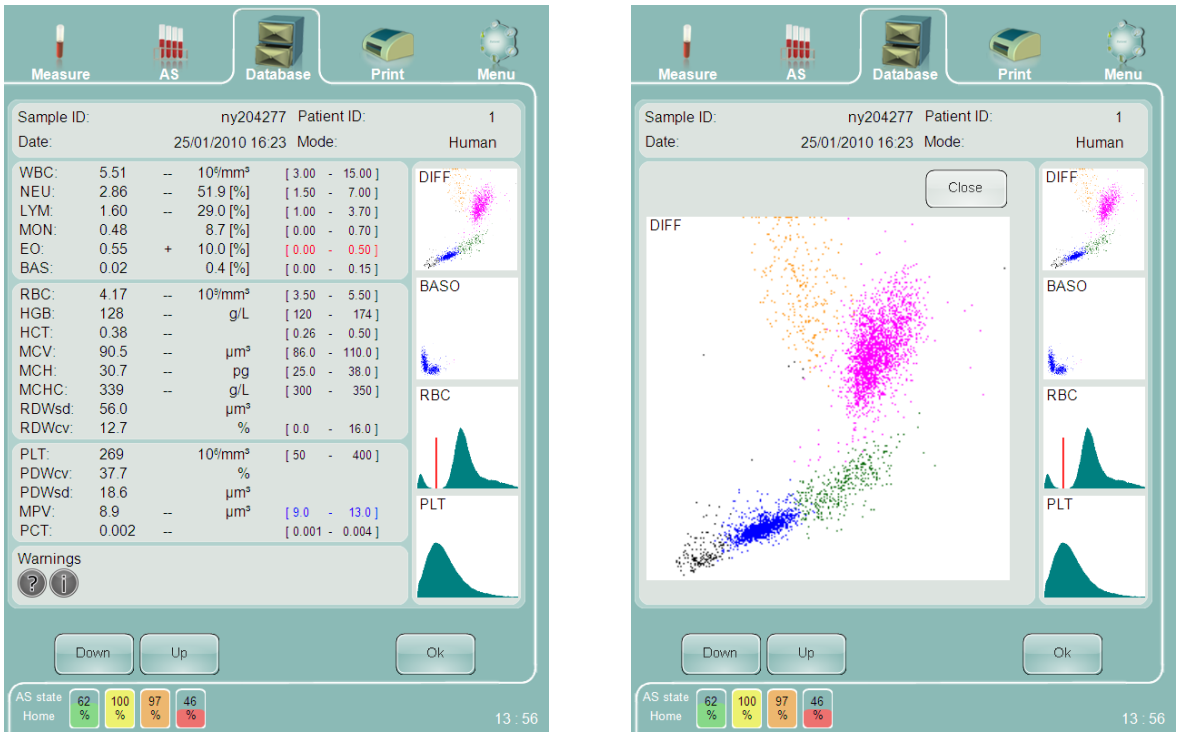


Figure 47. Results Display and Magnified Scatter Plot

Comparison of parameters to the normal range can be displayed numerically or graphically. See section 13.1 for more information on display of normal range status. Other kinds of flags are also displayed in the result screen.

See section 8 for detailed information about the ‘Hemolyzer 5’ result screen.

7.6 Printing Reports

Click or tap the Print icon at the top of the screen to send a report (or any displayed screen) to the external printer.

7.7 The Measurement Process

The ‘Hemolyzer 5’ analyzer measures 24 parameters of whole human blood samples. Internal dilutions are made to allow measurement of particles in the sample. Manual or automatic mode samples are processed in the same way.

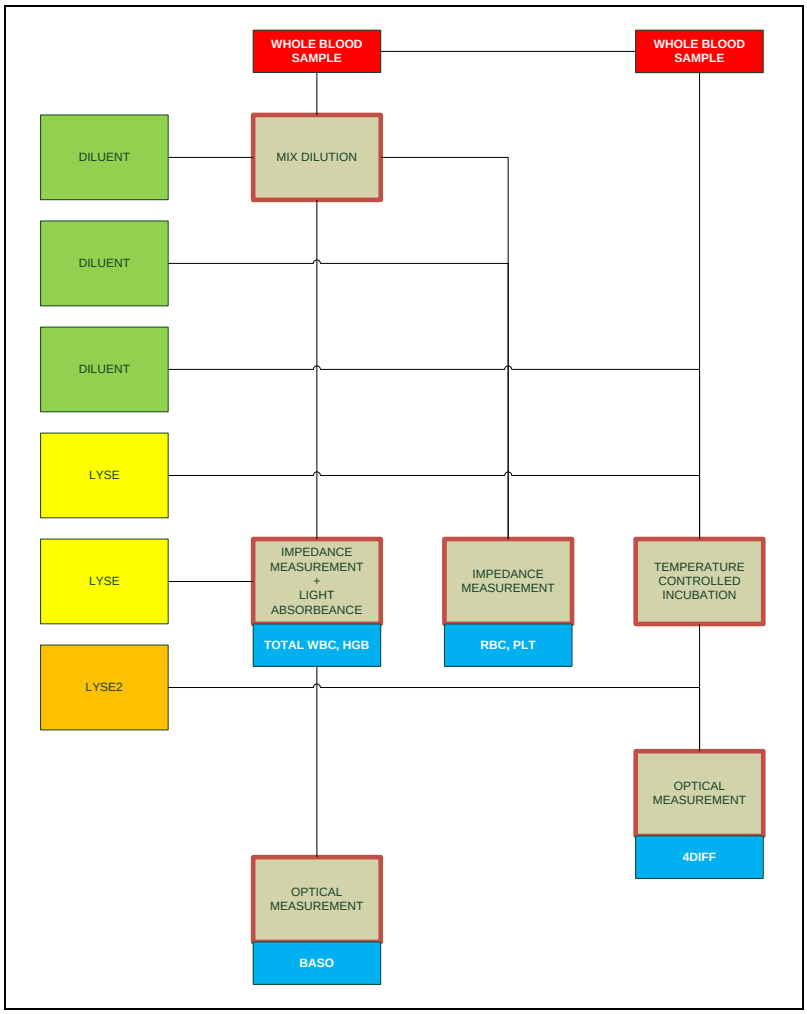


Figure 48. 'Hemolyzer 5' Measurement Process

When you present the sample tube and press the Start button, the 'Hemolyzer 5' rotates the sample rotor and takes the sample tube inside the analyzer. The piercing needle pierces the sample tube cap (if present) and aspirates approximately 110 µL of primary blood sample. Blood sensors ensure that the primary blood sample is continuous and free of major bubbles as it is moved to the shear valve. The shear valve separates the primary sample into further samples of exact volumes of blood that are distributed to provide dilutions for the RBC, WBC, HGB and 5 Diff population measurements. Lysing reagents are used to eliminate RBCs for dilutions that measure WBCs.

RBC/PLT and WBC are measured with impedance technology through 70 and 80 µm apertures respectively. Two portions of the sample are used for determining a five subpopulation differential of WBC in two independent 4DIFF and BASO measurements.

Sample results are displayed on the screen as the process is nearing completion. Results are stored in the internal database and transmitted to an external LIS if configured to do so. The 'Hemolyzer 5' performs a cleaning rinse of the internal pneumatic components and prepares to measure the next sample.

8 Result Interpretation

This chapter provides description about interpreting and understanding reports provided by the 'Hemolyzer 5' analyzer.

8.1 The Result Screen

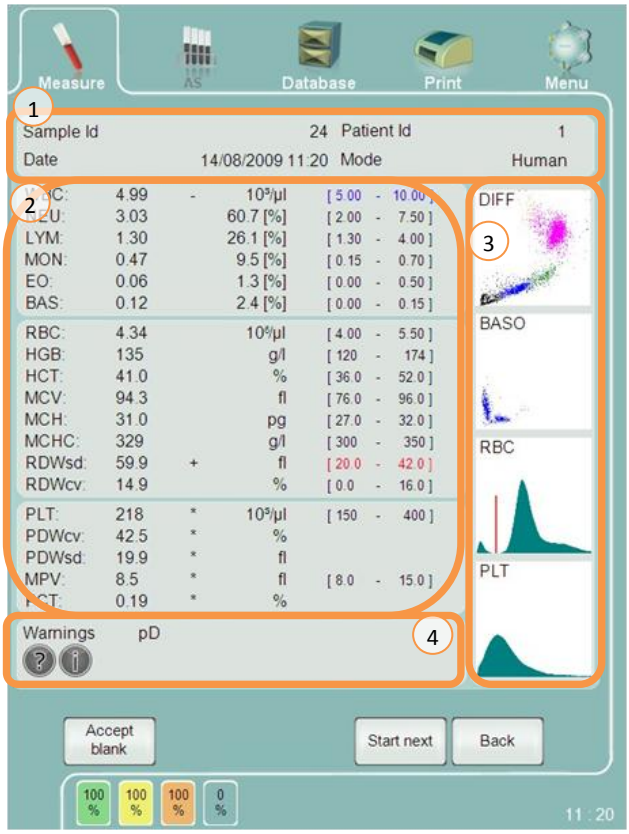

Measure
AS
Database
Print
Menu
1
Sample Id 24 Patient Id 1
Date 14/08/2009 11:20 Mode Human
2
LYM: 1.30 26.1 [%] [1.30 - 4.00]
MON: 0.47 9.5 [%] [0.15 - 0.70]
EO: 0.06 1.3 [%] [0.00 - 0.50]
BAS: 0.12 2.4 [%] [0.00 - 0.15]
RBC: 4.34 [4.00 - 5.50]
HGB: 135 g/l [120 - 174]
HCT: 41.0 % [36.0 - 52.0]
MCV: 94.3 fl [76.0 - 96.0]
MCH: 31.0 pg [27.0 - 32.0]
MCHC: 329 g/l [300 - 350]
RDWsd: 59.9 + fl [20.0 - 42.0]
RDWcv: 14.9 % [0.0 - 16.0]
PLT: 218 * [150 - 400]
PDWcv: 42.5 * %
PDWsd: 19.9 * fl
MPV: 8.5 * fl [8.0 - 15.0]
Warnings pD
4
DIFF
3
BASO
RBC
PLT
Accept blank
Start next
Back
100 %
100 %
100 %
0 %
11 : 20

Figure 49. 'Hemolyzer 5' Result Screen

The 'Hemolyzer 5' analyzer result screen is divided into 4 major areas:

1. Sample identification information: contains identifying information used to uniquely identify this sample's information.
2. Parameter information: contains parameter names, values, units, and normal range. Normal range, linearity, and high blank flags are also displayed in this area.
3. Histograms and scatter diagrams: Visual elements that provide information about the measured population dispersion. These are active elements that can be individually magnified by clicking or tapping.
4. Warning flags area: this area displays warning, interpretive, and morphological flags associated with this sample. If flag display overflows its assigned space, an ellipsis will be displayed and the user can click on the information icon to see a detailed display of flags.

8.2 Sample Identification Information

This part of the results screen contains information that uniquely identifies a particular sample run.

Sample ID	The Sample ID is the ID entered by the operator from a keyboard or hand-held barcode reader for a manually processed specimen. For automatically processed specimens, the sample ID can be read from a sample tube barcode or entered into a list for one of the automatic processing list modes. Sample IDs can be reused in the 'Hemolyzer 5' analyzer, but other identifying information together with the sample ID uniquely identify the sample run.
Patient ID	This is the patient associated with this sample run. If none was entered or selected, the default patient ID is set to 1.
Run Date/Time	This is the time and date that this sample was run.
Sample Mode	This is the sample mode selected for this specimen. Each sample mode applies a different set of normal ranges to this sample run.

Table 8. Sample Identification Information

8.3 Parameter Information

The parameter information area of the 'Hemolyzer 5' analyzer result screen lists information on 24 parameters.

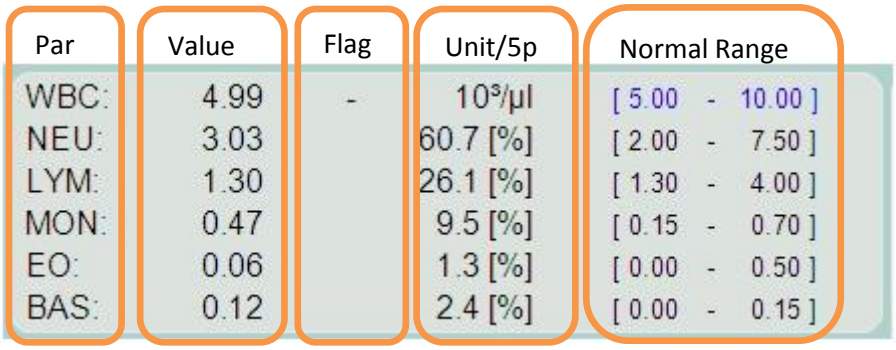


Figure 50. Parameter Information Display

Each row shows the parameter name, value, flags (normal range, linearity range, and high blank), units, and normal range. The units area displays the differential percentage for the five leukocyte subpopulations (NEU, LYM, MON, EO, BAS).

Parameter names are listed with their standard abbreviation. Parameter values are always displayed according to their selected unit. In case of error during sample evaluation, the software will display 'E' or" ---" signs to indicate the problems. Parameter values falling within the normal range are un-flagged and displayed with black text. Parameter values falling above the normal range are marked with a '+' and displayed with red text, and values falling below the normal range are marked with a '-', and displayed in blue text.

Normal range information can also be conveyed graphically as well as numerically. This setting can be changed in the Main menu/Settings/Customize panel.

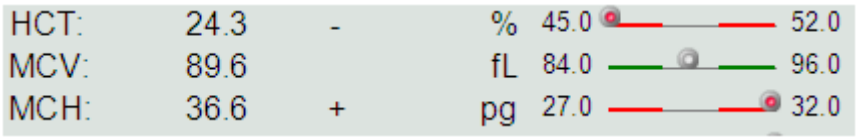


Figure 51. Graphical Normal Range Display

The flags displayed in the parameter information area are as follows:

Normal range flags	Normal range flags are raised when a particular parameter is above or below the normal range, which is defined for the patient profile currently in effect.		
Flag	Meaning	Hierarchy	Color Code
-	Parameter is under normal range	Lowest	Blue
--	Parameter is under the half of the low limit of normal range	Low	Blue
+	Parameter is over normal range	Lowest	Red
++	Parameter is over the double of the high limit of normal range	Low	Red

Table 9. Normal Range Flags

Linearity Range Flag	Linearity range flags are raised when a particular parameter is above or below the linearity range of the device.		
Flag	Meaning	Hierarchy	Color Code
*	The related parameter is out of the linearity range	High	N/A

Table 10. Linearity Range Flag

High blank flag	A high blank flag is raised when the blank measurement result of the particular parameter was higher than the blank limit.		
Flag	Meaning	Hierarchy	Color Code
!	The blank value of the related primary parameter is high	Middle	N/A

Table 11. High Blank Flag

8.3.1 Scatter Diagrams and Histograms

The 'Hemolyzer 5' analyzer displays the results of the optical measurements in scatter diagram representation. Scatter diagrams represent two-dimensional data. There are two scatter diagrams in the patient report: the 4-DIFF and BASO scatter diagrams.

The 4-DIFF scatter diagram displays cells identified after the first lysing and optical measurement process. Due to the measurement technology, cells are classified based on their optically detected properties: low and high angle scattered light intensity. The optical detector can measure the intensity of the light scattered or diffracted by each cell. One portion of this scattered light is proportional to size of the cell, the other is proportional to the complexity of the internal structures in the cell.

Cells in a leukocyte sub-population have similar light scattering properties, allowing them to be grouped together and identified separately from other cell types. Different colors are used to identify various populations of blood cells.

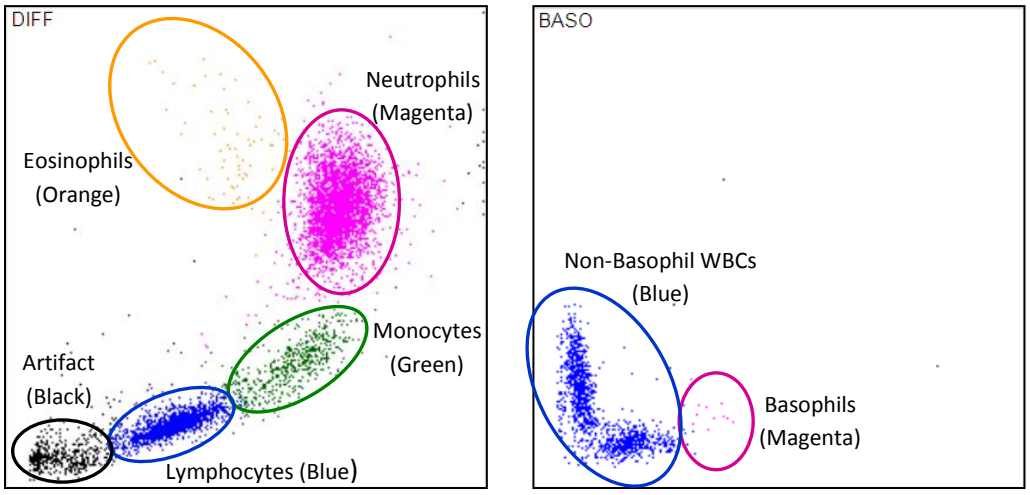


Figure 52. Result Screen Scatter Diagrams

RBC and PLT impedance-based measurements are represented by histograms. These diagrams show the number of cells on the Y axis and the cell size on the X axis. Smaller cells are displayed on the left side of the histogram, and larger cells are displayed on the right side. The height of the histogram at a given size represents the number of cells with that size. Greater histogram height indicates more cells.

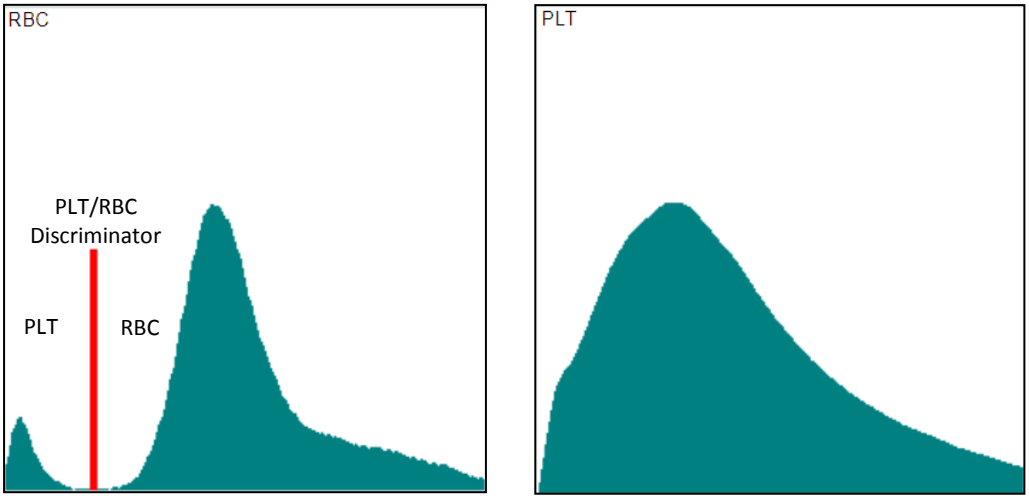


Figure 53. Result Screen Histograms

Both the RBC and PLT histograms can be zoomed. Discriminators (thresholds) are displayed with red color. Platelets are located on the leftmost part of the RBC histogram to the left of the red discriminator. The PLT histogram is a magnified version of this region.

8.3.2 Warnings

The warnings area of the result screen shows flags and messages related to the evaluation of the sample. Clicking or tapping the question mark icon on the left side of the warnings section of the results screen displays a detailed warnings panel. Click or tap OK to close the detailed warnings panel.

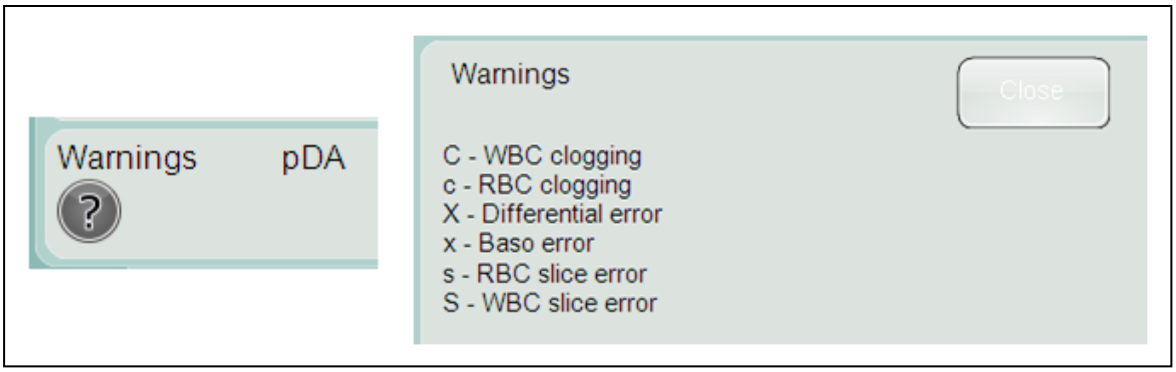


Figure 54. Warnings Section of Results Screen

The 'Hemolyzer 5' analyzer provides Warning flags, Morphological flags, and Interpretive messages in the Warnings panel. The following tables describe these flags and messages in detail. It also provides guidance on actions the operator can take to correct the problem described by the flag.

Warning flags		Warning flags are raised when the analyzer detects a problem in the analysis process that may cause incorrect or suspect results or the parameters in the valid blank measurement was too high.	
Flag	Meaning	Cause	Action
A	4 Diff Alarm	The 4DIFF populations are not clearly distinguishable on the scatter diagram.	If other parameters predict a 'normal' sample then perform a cleaning procedure and repeat the measurement. If 4DIFF results reported then treat them as 'reduced reliability'. If not all the parameters reported or the sample is predicted as pathological then perform a manual count on a stained smear.
B	WBC blank is high	WBC > WBC blank high limit	Check cleanliness of the reagents and the 'Hemolyzer 5'. Perform cleaning of the 'Hemolyzer 5'. Repeat blank measurement. See chapter: 6.2.5:Pneumatics start and blank measurement Treat WBC result as 'reduced reliability'.
b	RBC blank is high	RBC > RBC blank high limit	Check cleanliness of the reagents and the 'Hemolyzer 5'. Perform cleaning of the 'Hemolyzer 5'. Repeat blank measurement See chapter: 6.2.5 :Pneumatics start and blank measurement Treat RBC result as 'reduced reliability'.
C	WBC clogging	Drift in the probe voltage of the WBC capillary. The two main reasons for this drift are the misconnected reagent and the clogging of the capillary.	Check the reagent connections. Perform a cleaning procedure! See chapter: maintenance. Please repeat the measurement.
c	RBC/PLT clogging	Drift in the probe voltage of the RBC capillary. The two main reasons for this drift are the misconnected reagent and the clogging of the capillary.	Check the reagent connections. Perform a cleaning procedure! See chapter: maintenance. Please repeat the measurement.
D	MON - NEU alert	The MON and NEU populations are not clearly distinguishable on the scatter-gram.	If other parameters predict a 'normal' sample then perform a cleaning procedure and repeat the measurement. If MON, MON%, NEU, NEU% results reported then treat them as 'reduced reliability'. If not all the parameters reported or the sample is predicted as pathological then perform a manual count on a stained smear.
E	EO - NEU alert	The EO and NEU populations are not clearly distinguishable on the scatter-gram.	If other parameters predict a 'normal' sample then perform a cleaning procedure and repeat the measurement. If EO, EO%, NEU, NEU% results reported then treat them as 'reduced reliability'. If not all the parameters reported or the sample is predicted as pathological then perform a manual count on a stained smear.

Warning flags		Warning flags are raised when the analyzer detects a problem in the analysis process that may cause incorrect or suspect results or the parameters in the valid blank measurement was too high.	
Flag	Meaning	Cause	Action
F	Differential blank high	More than 100 cells detected during the ’4Diff-blank’ procedure.	Check cleanliness of the reagents and the ‘Hemolyzer 5’. Perform flow cell cleaning of the ’Hemolyzer 5’. Repeat blank measurement. See chapter: 6.1.5 :Pneumatics start and blank measurement Treat 4 Diff results as ‘reduced reliability’.
f	Baso blank high	More than 100 cells detected during the ’Baso-blank’ procedure.	Check cleanliness of the reagents and the ‘Hemolyzer 5’. Perform flow cell cleaning of the ’Hemolyzer 5’. Repeat blank measurement. See chapter: 6.1.5 :Pneumatics start and blank measurement Treat BASO result as ‘reduced reliability’.
H	HGB blank high	Last accepted blank result: HGB ≥ 10 g/l	Check cleanliness of the reagents and the ‘Hemolyzer 5’. Perform cleaning of the ’Hemolyzer 5’. Repeat blank measurement. See chapter: 6.2.5:Pneumatics start and blank measurement Treat HGB result as ‘reduced reliability’.
l	PLT URI	The PLT-RBC gap is not clearly detectable on the PLT-RBC histogram: small MCV, fractured RBC-s, aggregated PLT-s (cold blood), side-effect of blood-transfusion.	Check the sample quality. Repeat the sample. If the problem persists then perform a manual count on a stained smear.
M	Out of RBC linearity range	The RBC coincidence is over the limit: too high RBC count.	Check the sample homogeneity. Repeat the sample with manual pre-dilution.
m	Close to RBC linearity range	The RBC coincidence is close to the limit: too high RBC count.	Treat RBC result as ‘reduced reliability’. Check the sample homogeneity. Repeat the sample with manual pre-dilution.
O	High linearity range limit exceeded	If any of RBC,PLT or WBC results are higher than high linearity range limits.	Perform manual pre-dilution of sample and re-measure it.
o	Low linearity range limit exceeded	If any of RBC,PLT or WBC results are lower than Low linearity range limits.	None
p	PLT blank high	Last accepted blank result: PLT ≥ 15 * 103 cells/µl	Check cleanliness of the reagents and the ‘Hemolyzer 5’. Perform cleaning of the ’Hemolyzer 5’. Repeat blank measurement. See chapter: 6.2.5:Pneumatics start and blank measurement Treat PLT result as ‘reduced reliability’.

Warning flags		Warning flags are raised when the analyzer detects a problem in the analysis process that may cause incorrect or suspect results or the parameters in the valid blank measurement was too high.	
Flag	Meaning	Cause	Action
Q	MON - LYM alert	The MON and LYM populations are not clearly distinguishable on the scatter-gram.	If other parameters predict a 'normal' sample then perform a cleaning procedure and repeat the measurement. If MON, MON%, LYM, LYM% results reported then treat them as 'reduced reliability'. If not all the parameters reported or the sample is predicted as pathological then perform a manual count on a stained smear.
S	WBC measurement statistics warning	The distribution of the RBC detection changes in time. It points to clogging, non-homogeneous sample, cold sample, partial coagulation of the sample.	Perform cleaning of the 'Hemolyzer 5'. Check the homogeneity, the temperature and the coagulation of the sample. Repeat the sample.
s	RBC measurement statistics warning	The distribution of the RBC detection changes in time. It points to clogging, non-homogeneous sample, cold sample, partial coagulation of the sample.	Perform cleaning of the 'Hemolyzer 5'. Check the homogeneity, the temperature and the coagulation of the sample. Repeat the sample.
T	Blood detector error	BloodDetector malfunction (received signals are all zeros or not received signals)	Check BD and its connection to the LSDACQ card. Check sampling tube connection to BD.
u	Baso high	The number of the BASO population is high or there are lyse-resistant cells in the sample.	Repeat the measurement or perform a manual count on a stained smear.
V	WBC vacuum warning	There is a (partial) clogging or leakage in the RBC part of measurement system. A faulty/ worn-out pump can create vacuum errors as well.	Perform cleaning of the 'Hemolyzer 5'. Perform a self-test. If vacuum problems persist then call for service.
v	RBC vacuum warning	There is a (partial) clogging or leakage in the RBC part of measurement system. A faulty/ worn-out pump can create vacuum errors as well.	Perform cleaning of the 'Hemolyzer 5'. Perform a self-test. If vacuum problems persist then call for service.
W	Sampling warning	Blood Detector detected a sample volume that was too small.	Check sample volume in sample vial. Check sampling process. Re-run sample.
X	Differential error	Not enough cells detected during the 4DIFF WBC differentiating.	Perform a flow cell cleaning procedure! Repeat the measurement. If the problem persists then ask for service.
x	Baso error	Not enough cells detected during the Baso WBC differentiating.	If the total-WBC count is below 2 * 103 cells/µl then perform a manual count on a stained smear. Perform a flow cell cleaning procedure! Repeat the measurement. If the problem persists then ask for service.

Warning flags		Warning flags are raised when the analyzer detects a problem in the analysis process that may cause incorrect or suspect results or the parameters in the valid blank measurement was too high.	
Flag	Meaning	Cause	Action
Y	Differential percentage error	Algorithm error while distinguishing the WBC-s in the 4DIFF procedure.	Repeat the measurement. If the problem persists on a given sample then perform a manual count on a stained smear.
y	Baso percentage error	Algorithm error while distinguishing the WBC-s in the BASO procedure.	Repeat the measurement. If the problem persists on a given sample then perform a manual count on a stained smear.
Z	WBC noise high	During WBC count there is too much (more than 10% of the total) detected pulse on the first 10 channel of the 255 channel full range. This may be caused by lyse resistant RBC, electronic noise, contaminated WBC chamber or contaminated reagents.	Perform Clean process. Perform Hard Clean process.

Table 12. Warning Flags

Morphological flag		Morphological flags are raised when the presence of morphologically abnormal cell types such as immature granulocytes are suspected.	
Flag	Meaning	Cause	Action
B	Blasts		NOT FOUND
G	Immature granulocytes	The count in the region of (low - high angle scatter of Hemolyzer 5) where the Immature granulocyte typically located is > 3% of the total WBC count.	Perform a manual count on a stained smear.
L	Atypical lymphocytes	The count in the region of (low - high angle scatter of Hemolyzer 5) where the atypical lymphocytes typically located is > 1% of the total WBC count.	Perform a manual count on a stained smear

Table 13. Morphological Flags

Interpretive flag	Interpretive flags infer the presence of distributional abnormalities such as leukocytosis.
Flag	Meaning
Leukopenia	WBC --
Leukocytosis	WBC + or WBC ++
Neutropenia	NEU --
Neutrocytosis	NEU ++
Lymphopenia	LYM --
Lymphocytosis	LYM ++
Monocytosis	MON ++
Eosinophilia	EOS ++
Basophilia	BASO ++

Interpretive flag	Interpretive flags infer the presence of distributional abnormalities such as leukocytosis.
Flag	Meaning
Anemia	RBC - or RBC --
Polycythemia	RBC + or RBC ++
Microcytic RBC	MCV - or MCV --
Macrocytic RBC	MCV + or MCV ++
Hypochromic	MCHC - or MCHC --
Hyperchromic	MCHC + or MCHC ++
Anisocytosis	RDW + or RDW ++
Thrombocytopenia	PLT --
Thrombocytosis	PLT + or PLT ++
Microcytic PLT	MPV - or MPV --
Macrocytic PLT	MPV + or MPV ++

Table 14. Interpretive Flags

9 Database Functions

The ‘Hemolyzer 5’ database stores all measured data including sample results, QC, and patient data. Each sample result stored includes the complete parameter list, histograms, flags, and identifying data. The ‘Hemolyzer 5’ has a data capacity of up to 100,000 total records.

To activate Database panel, clicking or tapping the Database quick link on the top of the screen will take you to the database view from any screen.

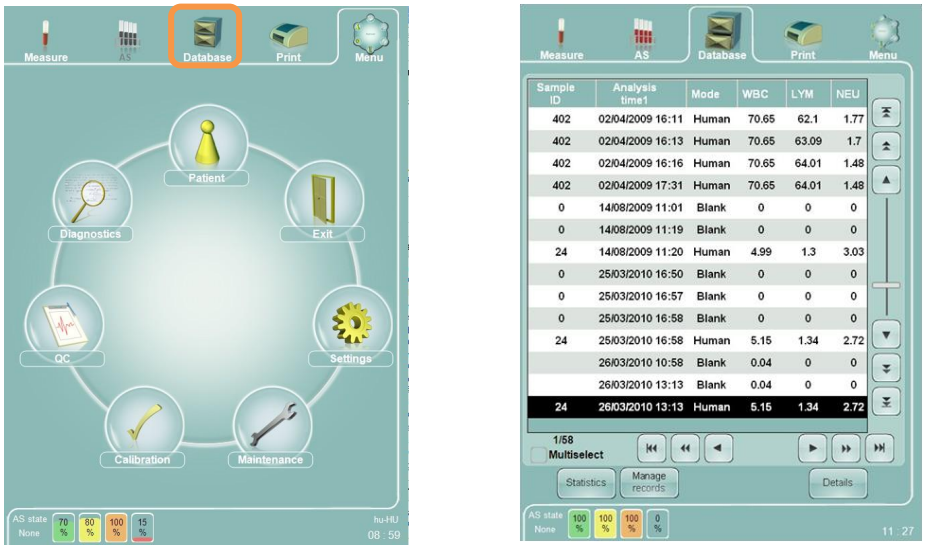


Figure 55. Accessing the Database

The database can be accessed at any time, even when processing samples in the background. You can return to the measurement panel anytime to view ongoing sample measurements.

9.1 Database Overview

The ‘Hemolyzer 5’ analyzer database provides a powerful, easy-to-use method of storing, accessing, and managing patient and sample result information. The database of the ‘Hemolyzer 5’ analyzer is capable of storing up to 100,000 measurement, control and patient records.

The database presents information in a table view of rows and columns. Each row in the database panel represents one sample measurement. Rows are also called ‘records.’ Each column in the database consists or sample identification information or measurement parameter results.

The database information can be scrolled using navigation buttons along the right and the bottom of the database view, or by a moving a vertical scroll bar. Database records can be selected individually or in groups. Detailed result views are available for selected database records. Selected records can be printed, sent to an LIS and exported into a tab file. Various sort options are provided for quickly finding results.

Database records can be exported for storage and backup. Exported database information can be later imported for review. Imported records do not become part of your ‘Hemolyzer 5’ analyzer’s database. They are only imported for viewing, but can be sorted, selected, and managed the same way as with regular data the stored inside the ‘Hemolyzer 5’ analyzer database.

The ‘Hemolyzer 5’ database displays two numerical counters separated by a slash under the left side of the database table. The left number is the number of selected rows, and the right number is the total number of rows in the database.

9.2 Scrolling the Database View

The limited size of the interactive database display acts like a viewport into the large amount of information inside your database. You can scroll the database view to bring desired information into view. The ‘Hemolyzer 5’ analyzer provides several powerful and easy-to-use scrolling methods. The numbered items below match the items in Figure 56 below.

1. The scrollbar: tapping, holding and moving the scrollbar labeled ‘1’ with the tip of your finger on the touch screen display will quickly scroll information in the vertical direction. Clicking and dragging with an optional external mouse will achieve the same effect.
2. Tapping or clicking the buttons labeled ‘2’ will advance the display by one line or one column.
3. Tapping or clicking the buttons labeled ‘3’ will advance the display by one page of information at one time.
4. Tapping or clicking the buttons labeled ‘4’ will advance the display to the first or last item in the list.

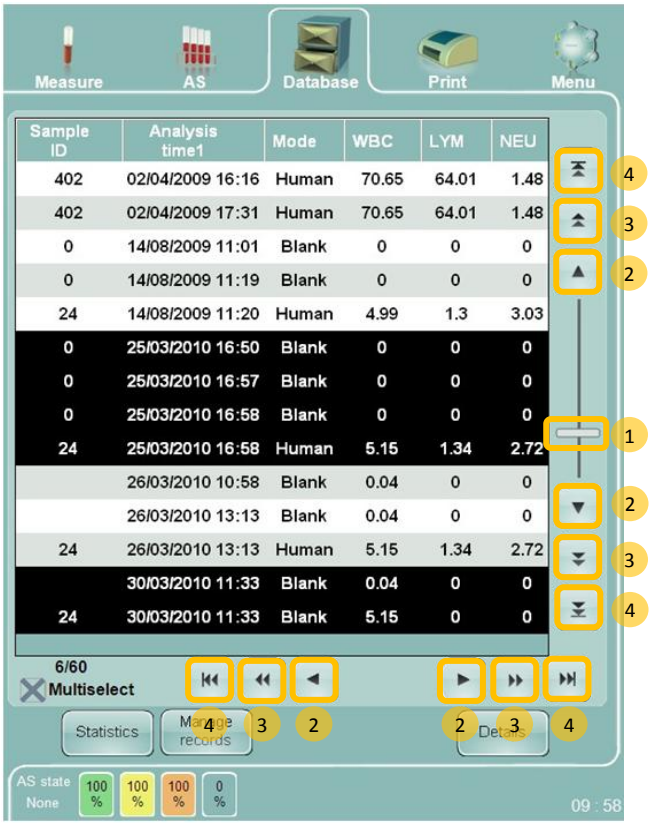


Figure 56. Scrolling and Selecting

9.3 Sorting Database Information

The database is sorted by Result ID by default. Clicking or tapping the following database column headings changes the sort order of the database records:

Sample ID	Sample ID entered by the operator or read from a sample tube barcode label

Patient	Identifier that associates a result record with a patient records
Analysis Time	Time and date this sample tube was analyzed
Result ID	Unique sequential identifier assigned by the 'Hemolyzer 5' to each records

Table 15. Database Sort Criteria

Clicking or tapping the same column heading again changes the ascending or descending order of values in the column.

9.4 Manual Selection of Database Records

Clicking or tapping on a row in the database display single-selects a row. Clicking or tapping it again de-selects the row. Selecting another row will de-select previously selected rows in single selection. Selected rows are highlighted with white text on a black background.

Checking the 'Multiselect' check box below the left side of the database table allows the selection of multiple rows. Tapping or clicking once selects a row, but previous selections remain selected unless you click or tap it again to de-select it. Un-checking the Multiselect check box will de-select all selected records.

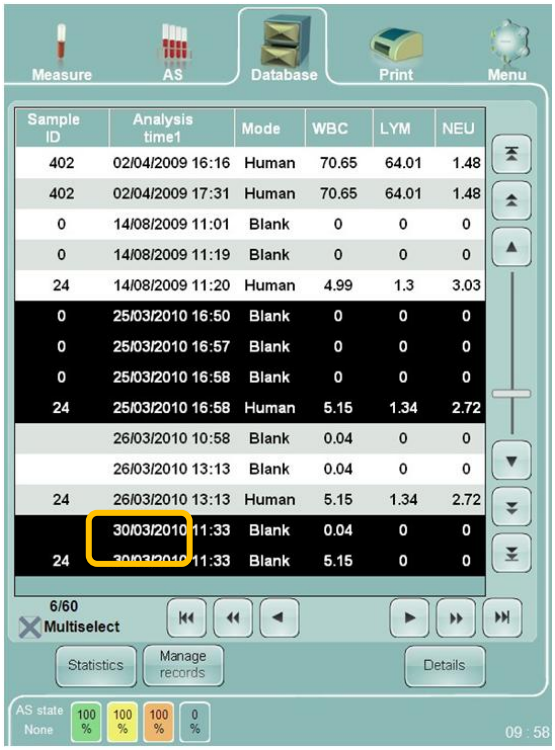


Figure 57. Multiselect and Multiple Selection

Multiple selections are useful for viewing, managing and quickly viewing statistics of only a few selected records.

9.5 Automatic Selection of Database Records

When the total number of records in a database becomes very large, manual selection of records can become difficult. The 'Select by' function in the Manage records panel provides the means to select a group of records automatically according to their identifying information. See section 9.8.1 for more information on the Select by database function.

9.6 Viewing Detailed Results

Multiple selection is also useful for viewing the detailed results of a few records rather than navigating through the database. After selecting several records, clicking or tapping the 'Details' button on the database panel will display the detailed results for the first record in the selection. Clicking or tapping the 'Up' or 'Down' buttons on the details screen displays the details of the next record in the selection.

9.7 Statistics

After selecting a group of records, click or tap the 'Statistics' button on the database panel to view the coefficients of variation (CV) associated with each of the 24 parameters. This function is useful to quickly measure the imprecision of multiple runs of the same sample.

9.8 Managing Database Records

'Hemolyzer 5' analyzer database management functions are accessed by clicking or tapping the 'Manage records' button to bring up the Manage records panel.

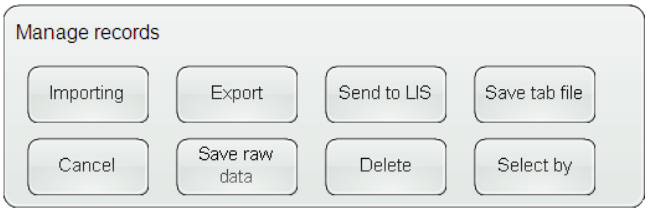


Figure 58. Manage Records Panel

All data manipulation actions that change the data stored in the 'Hemolyzer 5' database are logged in the 'Hemolyzer 5' log. If the multi-user mode is enabled, the name of the operator logged on at the time the data manipulation occurs will also be stored in the log.

9.8.1 Select By

Click or tap the 'Select by' button on the Manage Records panel to display the Select by panel. The Select by panel allows you to select a group of records with dates and Result IDs that match criteria entered into the panel.

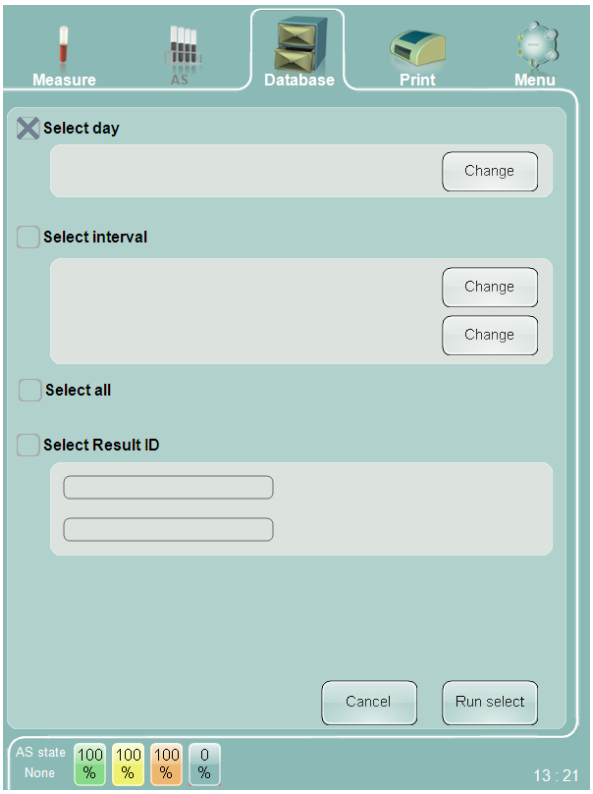


Figure 59. Select By Panel

The Select by panel provides various ways to select records. Only one of the four selection methods can be chosen.

Select day	Clicking or tapping the 'Change' button displays a virtual on-screen date keyboard. All records analyzed on the date entered will be selected.
Select interval	The two 'Change' buttons allow entry of a start and end date. All records on the start date, the end date, and all dates in between will be selected.
Select all	All records in the database will be selected.
Select Result ID	Entering one Result ID will select a record with the same Result ID. Entering two Result IDs will select a range of records including the start and end Result IDs.

Clicking or tapping the 'Run select' will create a multiple selection of all database records that match the criteria (if any). The 'Cancel' button returns to the database view and the current selection is not changed.

9.8.2 Importing

Clicking or tapping the 'Import' button displays a blank, modified version of the database panel.

Figure 60. Database Importing Panel

The database importing panel provides the following options:

- The 'Import' button brings up a panel to select previously exported database record files to load and view.
- 'Select by' performs the select by database function to select a group of imported records according to criteria entered by the operator.
- 'Details' views the detailed result information for all or a selection of imported records.
- 'Clear' removes selected records from the imported records table, but does not permanently remove the cleared records from the stored database file.
- 'Back' ends viewing of imported database information and returns to the 'Hemolyzer 5' stored database.

9.8.3 Export

The database export panel allows you to select a directory location to store records in a selection for backup or reference purposes. To back up all records in the database, first use the select by function to select all records in the database and export them using the export function.

Clicking or tapping the 'Export' button displays the database export panel.

Figure 61. Directory Panel for Data Storage

Introduce a USB storage device (USB hard drive, memory stick, etc.) into an available USB port on the back panel of the 'Hemolyzer 5' analyzer. Select the directory to store the exported data and press the 'Ok' button to start the export.

The file format of exported data is an internal format, and can only be read and interpreted by the 'Hemolyzer 5' analyzer using the Import function. Each database record is stored as an individual file with a '.rp' extension.

9.8.4 Send to LIS

The 'Send to LIS' button immediately transmits selected database records to the external LIS according to your LIS settings.

9.8.5 Save Tab File

The Save tab file function is used to archive database data to a tab separated text file. The 'Save tab file' button displays a directory panel like Figure 61, except that the file saved in the selected location is a tab separated text file rather than a database backup file. Tab separated text files can be loaded and viewed by a text editor or imported into spreadsheet software.

The filename created by the Save tab file function is generated automatically in the following format: TAB_YYYYMMDDHHMMSS.txt with the year, month, day, hour, minute, and second of the time when the operation started.

To archive database data using this function, insert a USB data storage device to one of the USB inputs on the back panel of the 'Hemolyzer 5' analyzer. Select the file location of your USB data storage device and click or tap the 'OK' button to begin the export.

See section 21.1.10 for detailed information on the format of the tab separated text file.

9.8.6 Save Raw Data

The save raw data function saves the raw data information associated with a selection of database records. Raw data files are only suitable for internal use by Analyticon staff. Your service engineer may ask you to save raw data files to help diagnose a service issue.

A confirmation password is required to save raw data. The default factory-set confirmation password is **555**. This password can be changed only by a Analyticon certified service engineer.

Insert a USB data storage device to one of the USB inputs on the back panel of the 'Hemolyzer 5' analyzer. Click or tap the 'Save raw data' button on the Manage records panel, then enter the correct confirmation password. Click or tap the 'Ok' button to display a directory panel like Figure 61. Select the file location of your USB data storage device and click or tap the 'OK' button to begin saving raw data.

9.8.7 Delete

The Delete function is used to delete records from a selection permanently from the 'Hemolyzer 5' analyzer database. To permanently delete records, select a group of records and click or tap the 'Delete' button on the Manage records panel.

To prevent accidental deletion of data, the 'Hemolyzer 5' requests the same confirmation password used in the save raw data function. After entering the correct password and clicking or tapping the 'Ok' button, the records will be permanently deleted.

The password to allow deleting records is: **555.**

10 Calibration

The ‘Hemolyzer 5’ analyzer must be calibrated in order to provide correct, reliable results. Calibration should be done at the following times:

- At initial installation
- After replacing any component critical to the dilution or measurement process
- Any time quality control shows a systematic error or is outside predefined limits
- At periodic time intervals determined by laboratory regulations

The ‘Hemolyzer 5’ analyzer calibration process consists of running a commercial calibrator material or a human whole blood sample with known parameter values multiple times. The known parameter values and the average values of multiple runs are used to calculate calibration factors. The new calibration factors take effect once they are accepted by the operator.

If you are using a human whole blood as a calibrator, the calibration target values must be measured on a reference analyzer according to applicable regulations, standards, or laboratory procedures.

An automated calibration procedure is provided that guides the operator through the calibration process and performs the calibration factor calculation. Calibration factors can also be modified directly without running a calibration procedure. Only the primary measured parameters are calibrated: WBC, RBC, PLT, HGB, MCV, MPV, and RDWcv.

To view the calibration functions of the ‘Hemolyzer 5’ analyzer, select the ‘Calibration’ icon on the main menu to display the calibration panel. The Calibration panel displays an option to calibrate the ‘Hemolyzer 5’ analyzer or to view prior calibrations.

Figure 62. Calibration Options

10.1 Calibrating the ‘Hemolyzer 5’

Selecting the ‘Calibrate’ option on the calibration options panel displays the calibration panel.

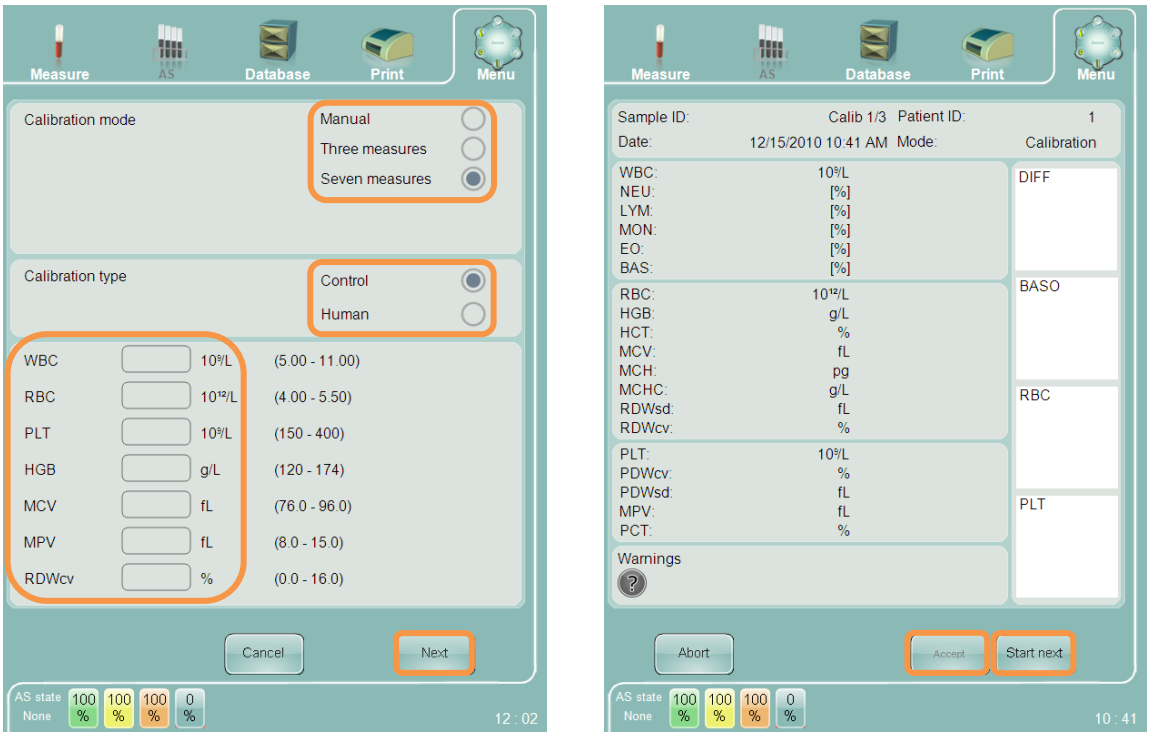


Figure 63. Calibration Panel and Calibration Run Result Panel

The limits of the calibration target values are linked to the normal range of the ‘Human’ sample mode.

	Commercial calibrator material and sample tube should be handled as a potentially biohazardous material. All applicable laws, regulations, and laboratory practices should be followed in the handling and disposal of calibrator materials.

To perform the automated calibration procedure, ensure that the ‘Hemolyzer 5’ pneumatic system is started up and that a valid blank measurement has been accepted. Perform the following steps:

- Prepare a sample tube with commercial calibrator material or human whole blood. Ensure that there is sufficient sample volume for three or seven consecutive runs.
- Place the calibrator sample tube in the sample rotor.
- Select ‘Three measures’ or ‘Seven measures’ according to your laboratory’s standard practices.
- Select ‘Calibrator’ for a commercial calibrator material or ‘Human’ for whole human blood calibration.
- Enter the calibration target values provided with your commercial calibrator material or the previously determined parameter values for human blood calibration.
- Click or tap the ‘Next’ button to begin the calibration process.
- The analyzer displays a blank result screen and begins sample measurement of the calibration material. Wait for the screen to be populated with results when sample measurement is complete.
- Click or tap the ‘Accept’ button if the measurement run is acceptable.
- Click or tap the ‘Start next’ button to begin the next calibration run. Selecting ‘Start next’ without accepting a calibration run discards the run. Selecting ‘Abort’ will abort the entire calibration procedure and discards all calibration results.

- The calibration procedure ends when three or seven accepted calibration runs are completed. The calibration factors are calculated and presented in the calibrator factor. The previous calibration factors and the coefficient of variation (CV) of the sample runs for each parameter are also displayed.
- Select 'Accept' to replace the current calibration factors with the accepted factors. Selecting 'Discard' eliminates the entire calibration process.

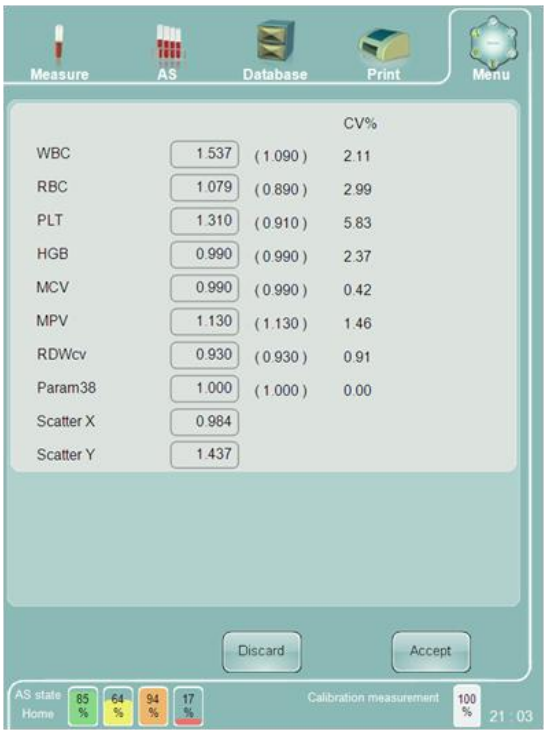


Figure 64. Calibration Factor Panel

The automatic calibration process can be skipped by selecting the 'Manual' calibration mode on the calibration panel and clicking or tapping the 'Next' button proceeds directly to the calibration factor panel for manual entry of calibration values. Manually entered calibration values can be accepted in the same way as calculated factors from calibrator sample runs, and are treated by the 'Hemolyzer 5' in the same way.

10.1.1 View Calibrations

The view calibrations feature is helpful for reviewing the calibration history for the analyzer. Increasing or decreasing calibration value trends over time may indicate a problem that requires service intervention.

To view the calibration history click or tap the 'View calibration' function on the calibration panel. The calibration history is presented in a table view that can be navigated in the same way as the database panel.

Any calibration can be deleted. Deleting the last calibration causes the 'Hemolyzer 5' analyzer to revert to the last accepted calibration.

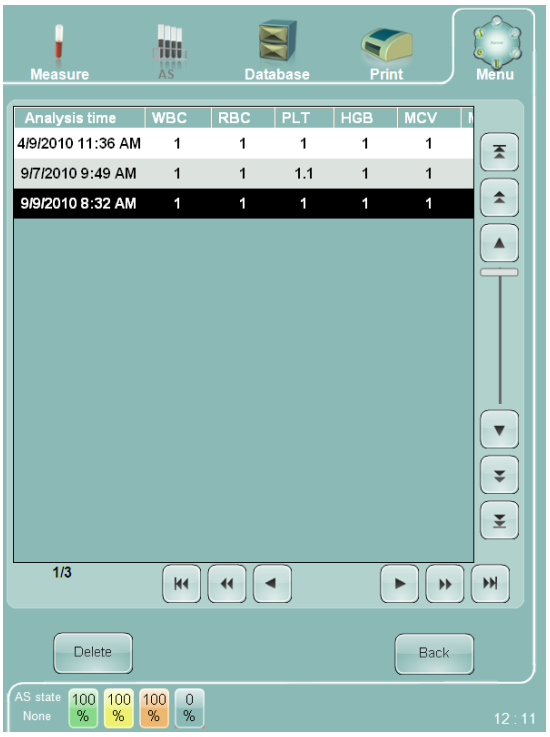


Figure 65. View Calibration Panel

To delete a calibration, click or tap the 'Delete' button. The system will ask you for a confirmation password to avoid accidental deletion of calibration data. The confirmation password is set at the factory to **555**, and can be changed by your Analyticon certified service engineer.

11 Quality Control

Regular use of quality control (QC) ensures that the 'Hemolyzer 5' analyzer is operating optimally. Stable recovery of standard QC material parameters assures the operator that the 'Hemolyzer 5' is operating consistently on a day-to-day basis and is functioning correctly.

By analyzing control materials on a regular basis, day-to-day reproducibility and general condition of the analyzer can be monitored. Target values and acceptable (tolerance) ranges for each parameter can be specified for an unlimited number of QC materials.

⚠	Control materials must be used before their expiration date. Always observe the control manufacturer's instructions for storage and use. Control materials must be well mixed before use.

Analyticon recommends the use of CBC-3K® controls from R&D Systems®.

The 'Hemolyzer 5' analyzer does not limit the number of QC material lots or the number of QC measurement runs that are stored in the control database. Each QC measurement run is saved to the selected QC material lot.

QC lots can be commercial control materials or a whole human blood sample whose parameter values and ranges are determined by other means. The advantage of a commercial control material is that is shelf life is much longer than human blood, allowing control of the analyzer for a longer period of time.

Controls in the 'Hemolyzer 5' are processed in manual mode only. To access the QC panel, select the 'QC' icon on the main menu.

Figure 66. QC Panel

11.1 Set QC Reference

Before taking any QC measurements, target values and acceptable ranges must be specified for a QC lot of control material. Click or tap the 'Set QC reference' button to display the Set QC panel.

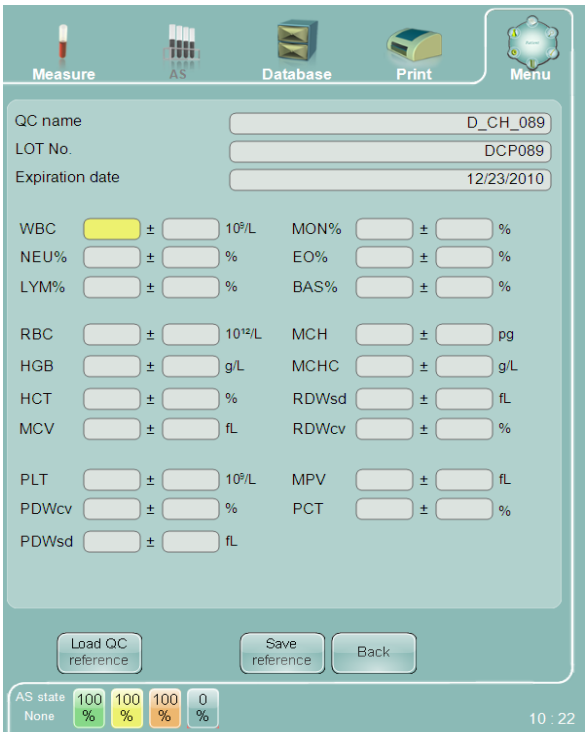
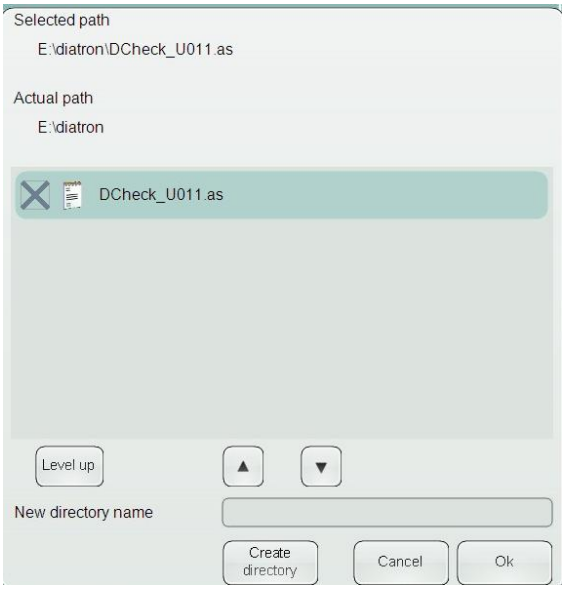


Figure 67. Set QC Reference Panel

The 'QC name' is the name that will be displayed for selecting the control to associate with a QC measurement. Enter the identifying information, and the target values and tolerance ranges for any parameters that are to be controlled with the 'Hemolyzer 5' QC system. To exclude a parameter from the QC procedure, leave its target value and tolerance range field empty. Press the 'Save reference' button after data entry is completed.

Tapping the "Load QC reference" button will allow filling QC material data electronically – using a file provided by the manufacturer of the analyzer. A dialog will open. Browse to the correct folder, and select the file by tapping the checkbox in front of the filename.



The file contains information for all three levels of the control material (Low, Normal and High). All three levels will be loaded into the system and will become selectable in the QC menu.

11.2 QC Measure

To run a QC measurement , please ensure that a valid blank measurement has been run and accepted. Associate the QC measurement to the correct control material lot by select the matching QC name in the selector below the 'QC measure' button on the QC panel. Place the control material sample tube in the sample rotor and click or tap 'QC measure'.

The QC measurement results will be added to the QC database and associated with matching QC material lot.

11.3 View QC References

Click or tap the 'View QC References' button to see a list of QC lot references stored in the 'Hemolyzer 5' analyzer control database. Target values and ranges can be viewed for any stored QC references.

11.4 View QC Data

Selecting 'View QC data' displays QC runs stored in the QC database in a table format that operates the same way as the 'Hemolyzer 5' analyzer database. QC measurement results will have sequential ID numbers. Option buttons are provided to switch back and forth between viewing QC data and viewing QC diagrams.

11.5 View QC Diagrams

Click or tap 'View QC diagrams' to see the Levey-Jennings charts for control measurements.

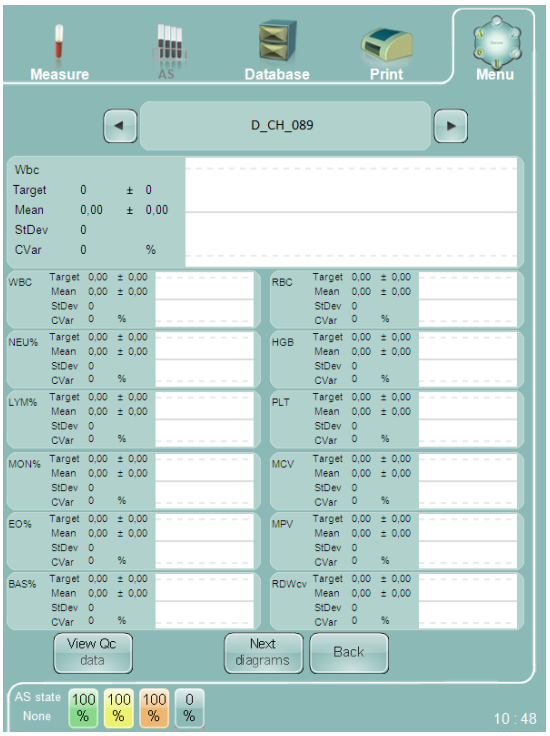


Figure 68. View QC Diagrams Panel

Means, standard deviations (StDev) and coefficients of variation (CVar) are calculated based on the QC analyses. The dotted lines delineate acceptable ranges on Levey-Jennings charts. Use the selector

control at the top of the panel to view graphical control information for other lots of control materials.

12 Patients

The ‘Hemolyzer 5’ analyzer allows the operator to define and store patients in the patient database during manual measurement. Patients can also be predefined while creating a list for one of the automatic processing modes.

Select the Patients icon on the main menu to display the Patients panel.

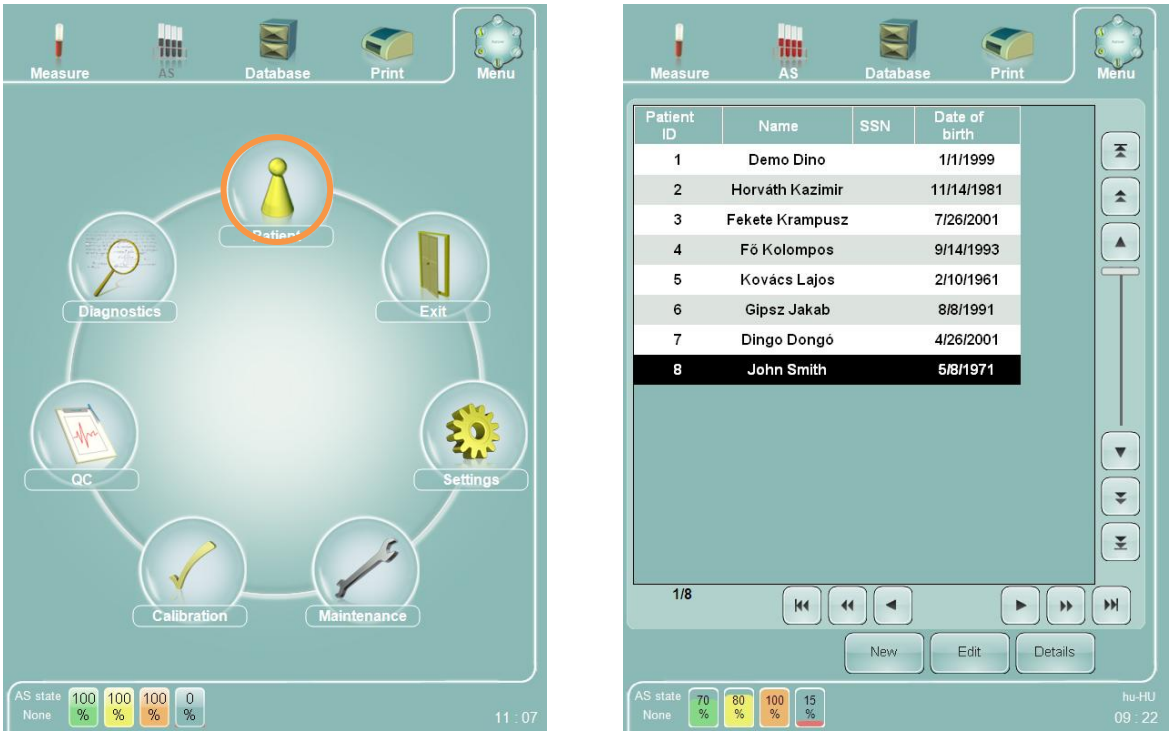


Figure 69. Patients Panel

The Patients panel displays patient information in the familiar table format of the ’Hemolyzer 5’ analyzer database, and operates the same way as the database panel. Use the ’New’ function to define new patients, and ’Edit’ to change existing patient information. ’Details’ displays patient data in a read-only mode.

The Patient panel can also be accessed by clicking or tapping the Name or Patient ID field in the Measurement panel. Two additional function buttons are available if the Patient panel is accessed from the Measurement panel.

The ‘Select ID’ function associates the currently selected patient to the sample measurement and returns to the Measurement panel. The ‘Cancel’ function returns to the measurement panel without selecting any patient to associate to the sample measurement.

You can select either Name or Patient ID to be displayed as the patient identifier in the Measurement panel by changing the settings in the ‘Patient’s displayed data’ in the Main Menu/Settings/Customize panel.

Figure 70. Edit Patient Panel

The ‘Save’ function saves any changes made. To discard any changes made, simply click or tap the ‘Back’ button.

13 Settings

The ‘Hemolyzer 5’ analyzer can be tailored to your laboratory’s needs by changing the settings. Click or tap the ‘Settings’ icon on the main menu to access the Settings panel.

Figure 71. Settings Panel

The options available on the Settings panel are:

- Customize
- Laboratory
- External Devices
- System
- Units
- Printer
- Profile Limits
- User

Clicking or tapping one of the buttons in the Settings panel displays the selected panel where settings changes can be made. Each panel has a ‘Back’ and ‘Save’ button. The ‘Save’ button saves any changes made and returns to the Settings panel, and the ‘Back’ button discards any changes and returns to the Settings panel.

13.1 Customize Settings

The Customize panel allows you to customize the ‘Hemolyzer 5’ analyzer user interface language and other preferences about the analyzer operation. Click or tap the ‘Customize’ button on the Settings panel to access the Customize panel.

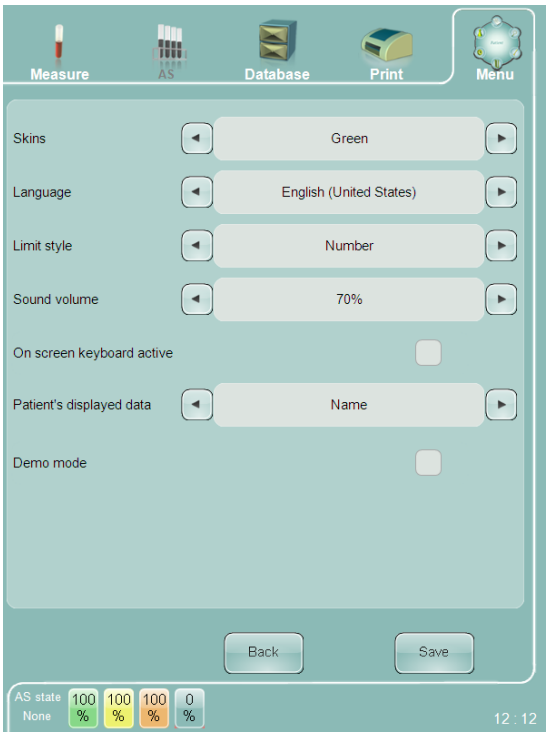


Figure 72. Customize Settings Panel

On the Customize panel, you can change the following settings:

- Language – select the language that the 'Hemolyzer 5' analyzer user interface uses to communicate with the operator. Available languages are English-US, English-UK, Hungarian, Polish, Turkish, and Italian.
- Limit style – select Number, Graphical1, and Graphical2 display modes to change the display method for parameters outside the normal ranges on the result screens and printed reports.
- Sound volume – modify the sound volume up or down
- On screen keyboard active – Select whether to use the on-screen virtual keyboards for displaying information, or an external keyboard.
- Patient's displayed data – choose Name or Patient ID as the patient identifier displayed in the Measurement panel.

13.2 Laboratory Settings

The Laboratory settings panel allows entry of seven lines of text up to 50 characters of descriptive information about the laboratory such as laboratory name, address, etc. All non-empty lines are displayed at the top of every result printout.

13.3 External Devices

The External Devices panel allows entry of external LIS settings. The 'Hemolyzer 5' analyzer support external LIS communications over a serial communications link using the Analyticon version 3.1 protocol. It also supports an Ethernet communications link over the HL7 version 2.5 protocol.

The External Devices panel lets you change the following settings:

- Sending port baud rate – select 9600 or 115200 baud for serial LIS connection.

- Automatic LIS – The ‘Hemolyzer 5’ will transmit every measurement result as soon as it is available if this check box is checked.
- LIS – the ‘Hemolyzer 5’ analyzer will use an Ethernet connection rather than a serial connection of this check box is checked.
- IP – the IP address of the external LIS computer should be entered here if an Ethernet LIS connection is used. IP addresses consist of four numbers from 0 to 255 separated by periods. See your IT administrator for more information about the IP address of your host LIS computer.
- Port – the port number of the external LIS computer should be entered with here with nor commas if an Ethernet LIS connection is used. Ports are a single number between 0 and 65535. See your IT administrator for more information about the port number of your host LIS computer.
- Bidirectional LIS – check this check box if the LIS computer will download lists for one of the list modes for automatic sample processing.

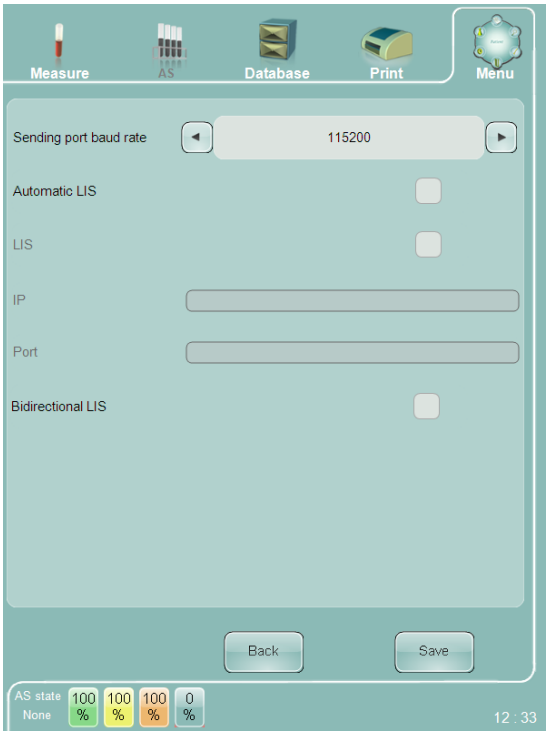


Figure 73. External Devices Settings Panel

13.4 System Settings

System settings change various options about the operation and behavior of the ‘Hemolyzer 5’ analyzer.

The System settings panel lets you change the following settings:

- Waste container volume – select 10L, 20L, or None. Selecting 10L or 20L changes the waste container tracking display behavior in the reagent status area at the bottom of the screen. Selecting None assumes waste is being drained directly into the laboratory drain and disables waste container tracking.

- Database display limit – select All or Last month to change the number of database records displayed in the database panel. Last month only displays the last 30 days of measurement results, and All displays all measurement results stored in the ‘Hemolyzer 5’ database.
- Use only Sarstedt Monovette tube from sample rotor – Check this check box to change the sampling depth for manually presented tubes at the sample rotor to accommodate Sarstedt Monovette tubes. Uncheck this check box to manually process standard sample tubes. This setting does not affect automatic sample processing with the optional Autosampler, which is able to recognize tube types and change sampling depth automatically.
- Standby time – This defines the time period of inactivity before the analyzer automatically leaves the ready state and drains the pneumatic components to prepare for overnight standby. If this time is set to zero, the analyzer will never enter the standby state automatically.
- Offline rinsing frequency – this defines the time period between automatic fluidic operations to ensure that fresh reagents are available in critical pneumatic components so that the analyzer can quickly return to the ready state from standby. If this time is set to zero, the analyzer will never perform automatic fluidic operations while in the standby state, but may increase the amount of time needed to return to the ready state from standby.
- Screen saver – this defines the time period of inactivity before the analyzer automatically starts the screen saver. Entering a time of zero prevents the analyzer from every starting the screen saver.
- Special flags (G, A) – Checking the check box disables the generation, storage, LIS transmission and display of the G and A flags on the screen, printout.

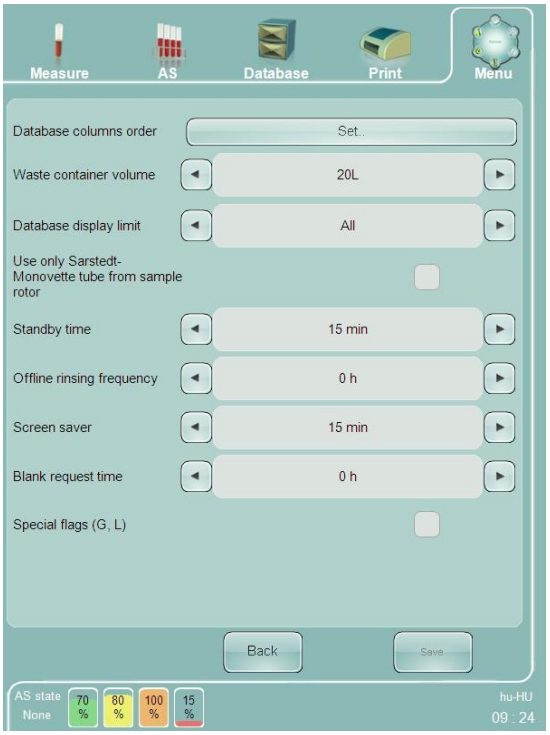


Figure 74. System Settings Panel

13.5 Units

The Units panel allows the user to choose which units are displayed for certain parameters.

The following options are available on the Units panel:

- HGB unit – choose g/dL or g/L to change the displayed units for the HGB and MCHC parameters.
- Count unit – Choose cells/µL or cells/L to change the displayed units for the parameters in the table below.

Parameter	Cells/µL	Cells/L
WBC	10^3/µL	10^9/L
LYM	10^3/µL	10^9/L
NEU	10^3/µL	10^9/L
MON	10^3/µL	10^9/L
EO	10^3/µL	10^9/L
BAS	10^3/µL	10^9/L
PLT	10^3/µL	10^9/L
RBC	10^6/µL	10^{12}/L

Table 16. Count Unit Parameters

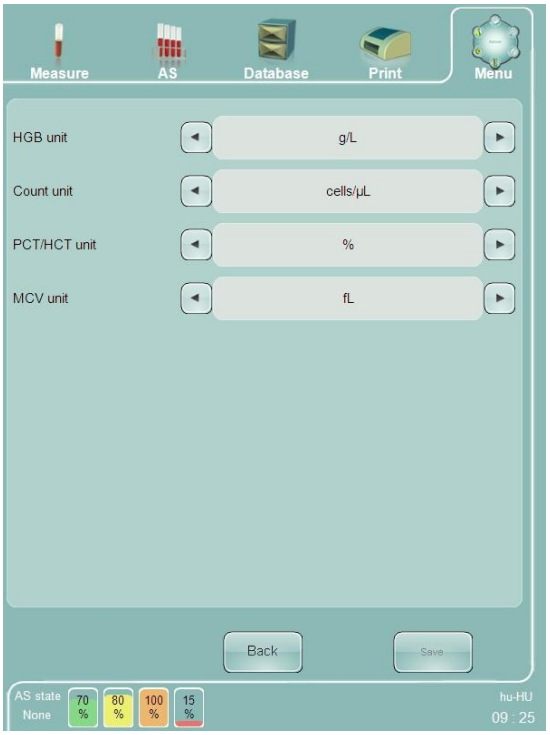


Figure 75. Units Settings Panel

13.6 Printer Settings

The Printer Settings panel lets you choose which installed printer to use, view the status of the printer, and change the print behavior of the analyzer during operation.

The following options are available on the Printer Settings panel:

- Printer – select an installed printer to use.
- Printer status – indicates the status of the currently selected printer.

- Color printing – check this check box to print in color, or uncheck to print in black and white.
- Double sided printing – check this check box to print on both sides of the paper, or uncheck to print on one side only. This option is only available if your installed printer supports double-sided printing.
- Items in queue – indicates how many printouts are currently waiting in the printer queue.
- Cancel all jobs – Click or tap this button to cancel printing and clear all items waiting in the printer queue.
- Printout format – select Default, Wide names, or User printout formats.
- Automatic print – check this check box to print every sample or control as it is run.
- Abort – press this button to abort automatic print.
- Logo visible – check this box to print the Analyticon logo on every printed report.

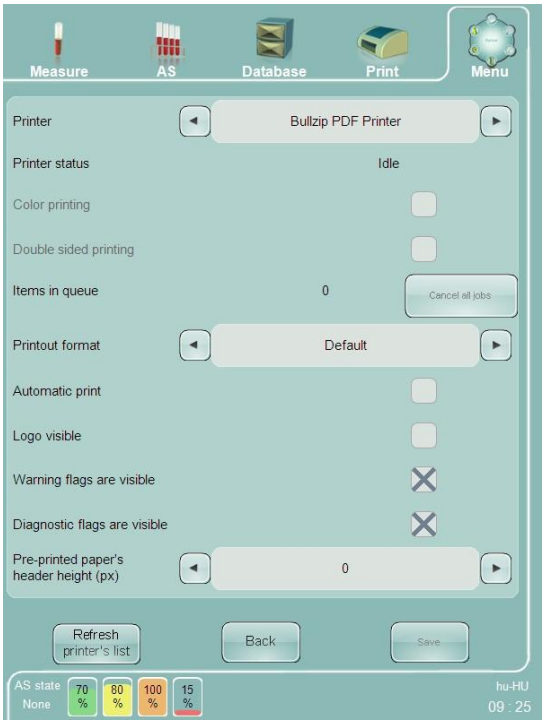


Figure 76. Printer Settings Panel

13.7 Profile Limits Settings

The Profile Limits settings are used to view and modify the normal ranges associated with the 'Hemolyzer 5' analyzer's five sample modes: Human, Male, Female, Alternate 1, and Alternate 2.

The control at the top of the panel selects one of the five sample modes. The panel is then populated with the lower and upper limit values for each of the 24 parameters. Modify the values as needed, then click or tap 'Save' to save the new values and return to the Settings panel, or select Back to discard any changes and return to the Settings panel.

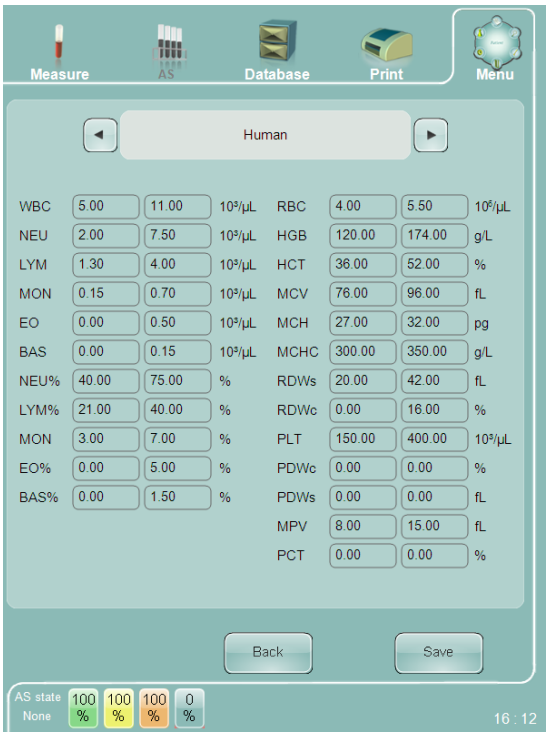


Figure 77. Profile Limits Settings Panel

13.8 User Settings

The User Settings panel allows administrators to delete users, or assign administrator rights.

Figure 78. User Settings Panel

Users with Administrator privileges can have access all over the system. Only an administrator user can grant or revoke administrator rights.

Regular users have limited access to the system. A regular user is

- allowed to modify Settings / Customize only (language, skin, sound volume)
- allowed to run and monitor QC measurements, but cannot define QC target values
- not allowed to perform Calibration

13.9 Date and Time Adjustment

Double-click or tap the time display on the bottom right side of the screen to display a time/date settings panel. Change the time and date as needed and select ‘OK’ to save or ‘Cancel’.

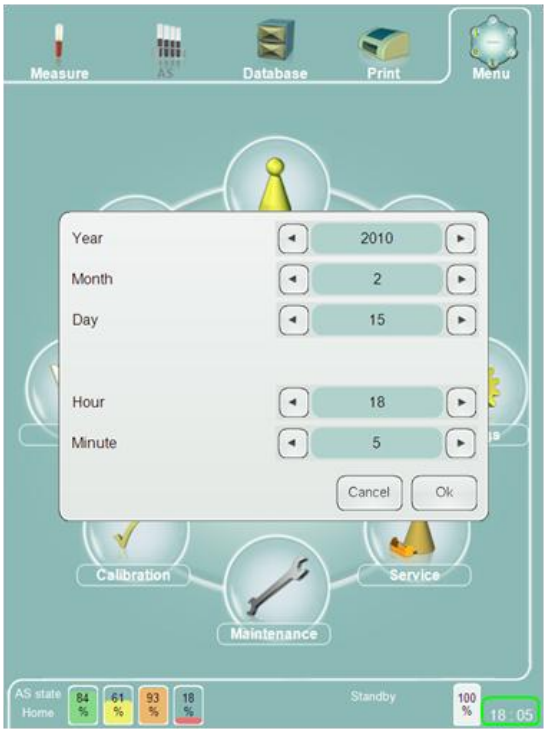
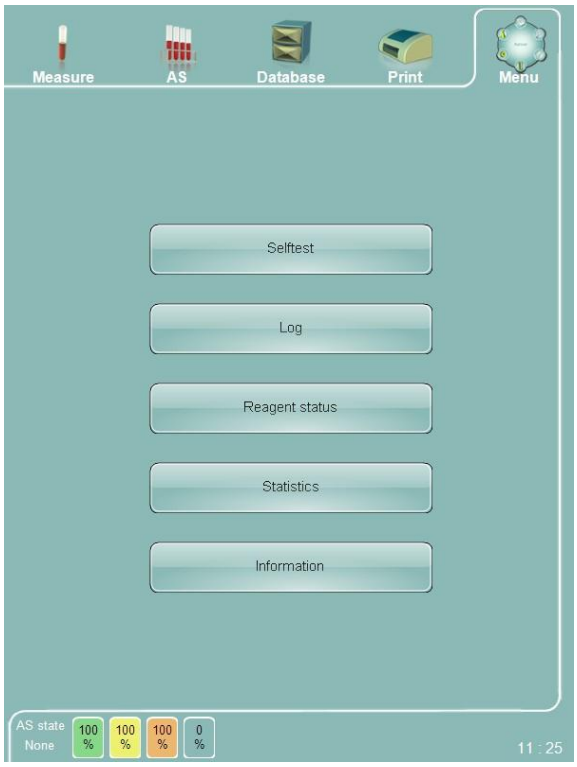


Figure 79. Time/Date Settings

The ‘Hemolyzer 5’ analyzer does not support automatic time zone or daylight savings time changes. Please change the time and date manually as needed.

14 Instrument Diagnostics

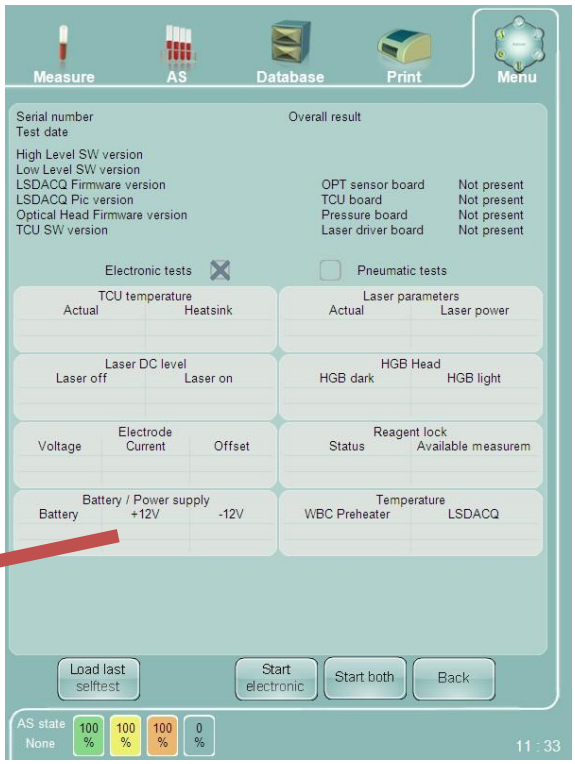
This section allows performing diagnostic steps and checking operation history, or so-called log files.

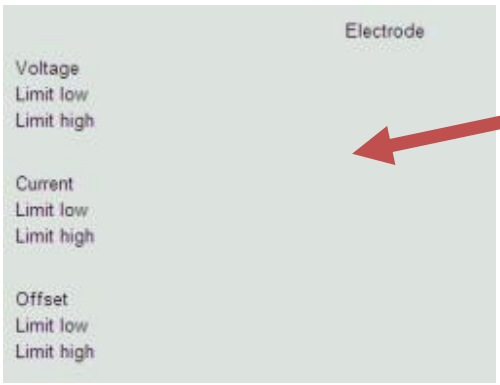


14.1.1 Self Test Of The Analyzer

Initiating a self test will test the key functions and components of the analyzer. The process takes approximately one minute and gives evaluation of each parameter. The acceptable ranges of each tested parameter or function can be found in the following table.

Tapping any tested parameter's small box gives detailed information of the parameter, limits and comments.





By using the "Load last selftest" function you can check the results of the previous self-test sequence.

Self test checks parameters for the ranges defined below:

Big puffer time Generate 3000 - 13000sec Release 3000 - 5500sec	Small puffer time Generate1 800 - 4000sec Generate2 800 - 4000sec Release 500 - 2000sec
Big puffer drift Maximum 540 - 560mBar Minimum 530 - 560mBar Drift -5 - 15mBar	Small puffer drift Maximum 225 - 235mBar Minimum 215 - 235mBar Drift -5 - 15mBar
Max vacuum P1 Maximum: 550 1000 mBar Time:0 – 6000 ms	Max vacuum P2 Maximum550 1000 mBar: Time: 0 – 6000 ms
Pump status Pump1 1 - 1 Pump2 1 – 1	Null pressures Sheath -20 - 20mBar Capillary -20 - 20mBar Chamber -20 - 20mBar
Noise/Pulse pls/5sec 0 - 2000 pulses 20000pls 19990 - 20050 pulses	HGB head HGB Dark 0 - 3000 pulses HGB light 3000 - 60000 pulses
TCU temperature Actual Reference +- 0.2 °C Sink 0 - 55°C	Laser parameters Reference +-10% Laser power 32.0 – 128.0
Laser DC level Laser off 0 - 0.05mV Laser on 0.10 - 0.45mV	HGB head HGB Dark 0 - 3000 pulses HGB light 3000 - 60000 pulses
Electrode Voltage 45 - 55V Current 620 – 680µA Offset -3.0 - 1mV	Reagent lock Status: UNLOCKED / LOCKED / NA Available measurements: none
Battery /Power supply Battery voltage 2.7 - 3.3V +12V 11.4 - 12.6V -12V -12.6 - -11.4V	Temperature WBC pre-heater: none (LSDACQ v3.0), 34.0 -38.0 (LSDACQ v3.1) LSDACQ: none

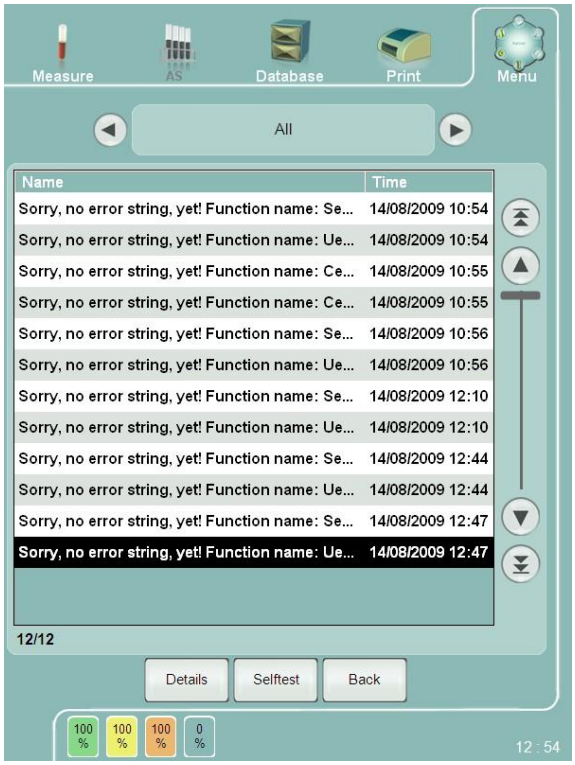
If any of the values falls outside the above limits, the SW is going to list the errors on the self test report screen.

14.1.2 Daily Log

The log option is included for service or troubleshooting purposes. It lists events and possible problems related to operation or measurements.

By using the swap-box on the top of the panel you can change if

All the log entries are displayed;
The error message are displayed only;
Pneumatic errors
Software errors
User actions
System actions

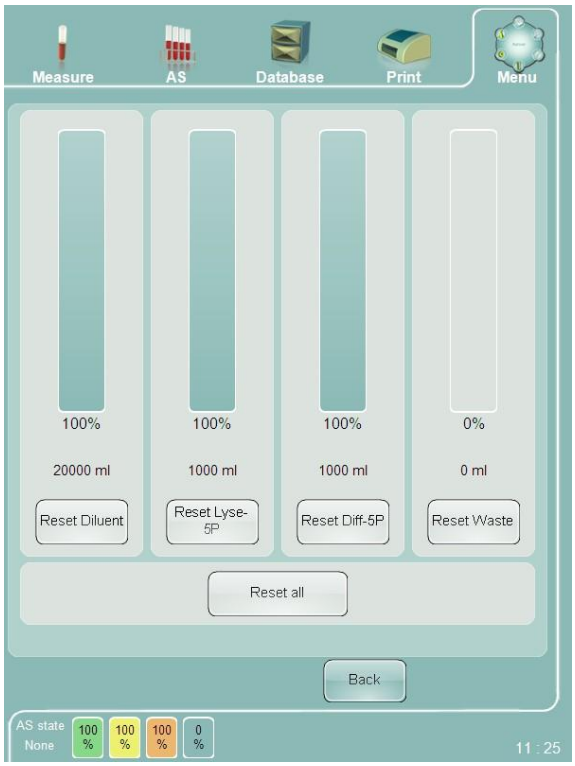

Measure
AS
Database
Print
Menu
All
Name
Time
Sorry, no error string, yet! Function name: Se... 14/08/2009 10:54
Sorry, no error string, yet! Function name: Ue... 14/08/2009 10:54
Sorry, no error string, yet! Function name: Ce... 14/08/2009 10:55
Sorry, no error string, yet! Function name: Ce... 14/08/2009 10:55
Sorry, no error string, yet! Function name: Se... 14/08/2009 10:56
Sorry, no error string, yet! Function name: Ue... 14/08/2009 10:56
Sorry, no error string, yet! Function name: Se... 14/08/2009 12:10
Sorry, no error string, yet! Function name: Ue... 14/08/2009 12:10
Sorry, no error string, yet! Function name: Se... 14/08/2009 12:44
Sorry, no error string, yet! Function name: Ue... 14/08/2009 12:44
Sorry, no error string, yet! Function name: Se... 14/08/2009 12:47
Sorry, no error string, yet! Function name: Ue... 14/08/2009 12:47
12/12
Details
Selftest
Back
100 %
100 %
100 %
0 %
12 : 54

14.1.3 Reagent Status

Actual level of reagent bottles is accessible from the menu system.

The analyzer has built-in reagent consumption calculators. The calculated level of each reagent is indicated on the screen. The height of the bar shows the level in the container. These levels are also indicated on the screen in the status area. Hemolyzer 5 send special message if any of the reagents are running low. Check and change the reagent container and reset the reagent status bar on the screen.

If the reagent-locking feature is activated then the resetting of the ‘Lyse’ reagent activates the uploading of the measurement count from the hardware-key. If the reagent-lock is in use then please connect the hardware key when resetting the ‘Lyse’ reagent-level.



14.1.4 Statistics

This menu item will display number of measurements and number of possible failure events experienced during operation. Statistical data can be reset by a certified service engineer only.

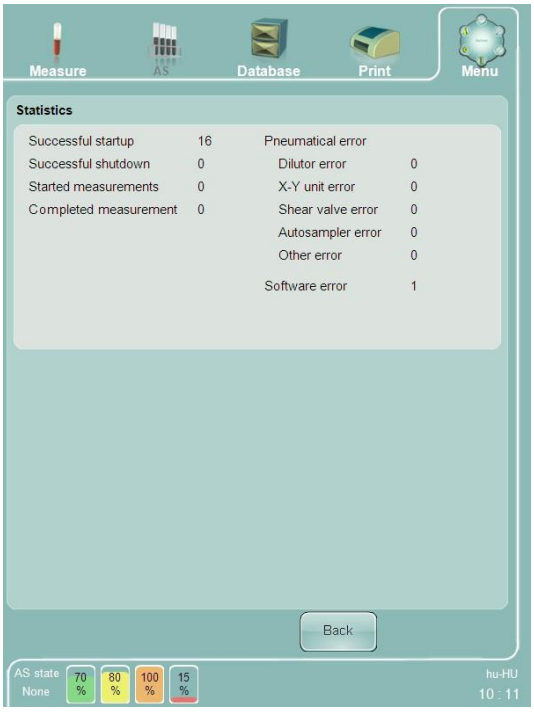


Figure 80. Statistics display

14.1.5 Information

This menu item displays instrument specific data (serial numbers, SW versions). These data are important for maintenance purposes. Your service engineer will ask for these before a service visit.

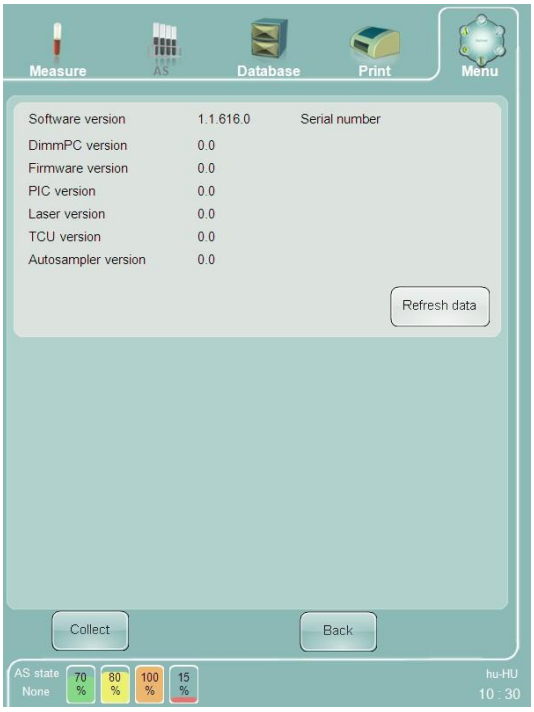


Figure 81. Statistics display

15 Maintenance

To ensure reliable operation, regular maintenance, or occasional corrective actions are required. This chapter describes necessary procedures and steps required to keep your analyzer in a good operating condition.

Hemolyzer5 is a complex automated hematology analyzer. Special 'Analyticon Hemolyzer5 Service Training' is required to resolve major problems occurring during operation. Electrical and moving parts should always be serviced by trained person.

There are, however some maintenance actions the operator should perform to keep the analyzer in a reliable and clean state.

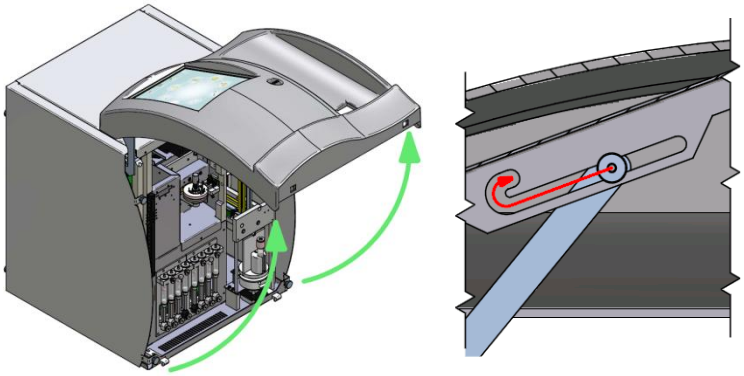
Any elements inside the analyzer like tubes, valves, chambers, containers should be handled as a potentially biologically and chemical dangerous material and have to observe the related law and follow the hospital handling instruction during disposal.

15.1.1 Opening The Front Panel

To access the pneumatic system, and to be able to perform some maintenance actions, you have to be able to open the front panel of the instrument.

Make sure that nothing is placed on the top, or in front of the analyzer. Grab the lower sides of the front panel, gently pushing the sides. Pull the lower part towards you, and lift it up.

Upon opening, a lever becomes visible. Make sure to tilt the front panel upwards so that you can push the lever into the secure position.

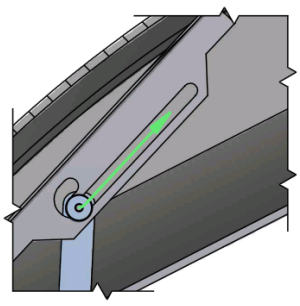


15.1.2 Closing The Front Panel

Do not push on the front panel while the security level is in the "lock" position.

Gently lift the front panel so that the security support lever can be moved to the free position.

Gently lower the front panel. When it reaches its lowest position, gently push on the front side to click the lock-levers in place.



15.1.3 Removing The Side Panels

With the front panel open and secured, thumb screws become visible. Both side panels are fixed to the instrument with these screws: 2 in the front, and 2 in the back. The screws are designed to stay on the analyzer to avoid losing them.

Left side covers valves and measuring chambers. It needs to be removed if chamber cleaning is requested by the analyzer.

Right side covers sampling unit and wash head and sampling needle. You need to open the right side if wash head needs to be cleaned or replaced.

After removing the cover, potentially hazardous parts become accessible, electronic boards, motors, moving parts, sampling needle, chambers, tubes and valves.

These components may cause injury, or can get damaged if handled incorrectly. Only certified personnel should open the covers. Running measurements with opened cover is not recommended due to the risk of possible injury. **Always wear safety gloves while performing maintenance actions.**

When reinstalling side panels, always make sure to re-tighten the thumb screws.

15.1.4 User Maintainable Parts Of The Analyzer

There are three user maintenance points in Hemolyzer 5

Shear valve: this is a key component and is responsible for correct sampling and diluting procedures.
Wash head: key component in keeping the sampling needle clean and thus ensuring reliable piercing and sampling procedures
Measuring chambers: contamination induced problems (noise, high blank values) can be resolved by cleaning the plastic chambers

General precautions: Always wear protective gloves when working on internal parts of the analyzer.

15.1.5 Maintenance Programs In The Analyzer

Maintenance functions can be accessed from the menu system.

Cleaning

Shear valve cleaning: drains the shear valve to let the user open and clean the ceramic valve.

Rinse: washes the tubing system
Clean: cleans the system with external cleaning reagent introduced through reagent inlets
Hard clean: performs a cleaning of measurement chambers and connected tubing. The software is going to prompt the user to add 0.5ml cleaning solution to the specified chamber(s). Add the correct amount of liquid. Higher volume of liquid added can result in overfilling the chamber(s) and thus can cause leakage.

Drain puffers

Internal Diluent reservoir; Flow cell
Can also drain internal chambers individually, or all puffers together.

Empty chamber

Drains chambers individually, or all chambers together.

Prime - Primes reagents individually, or all reagents together.

Fill Fill: Initial filling of the system with liquids. This must be performed PRIOR to first use of the instrument after installation.

Touch-screen

Touch-screen calibration. The software will instruct you to tap specific areas of the display. This is going to help calibrate the touch sensitive surface.

15.1.6 Cleaning The Shear Valve

Any salt build-up on the inner surface of the shear-valve may cause malfunction during operation. **To avoid this problem, it is recommended to clean the shear valve after every 1500 samples.**

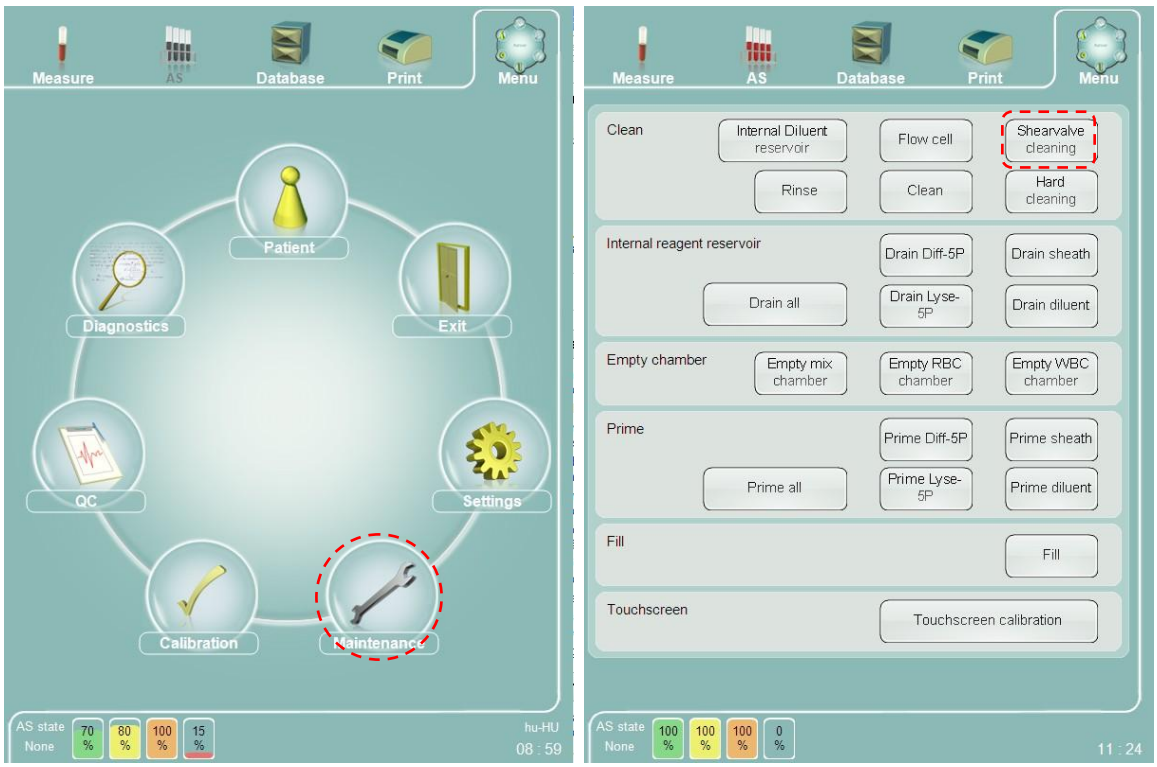
You need the following materials to complete the shear-valve cleaning:

A piece of soft cloth dampened with water;
A piece of soft, dry cloth;
A piece of lint-free soft, dry-cloth (like a non-woven sheet);
A pair of gloves;
A pair of tweezers;
A few tooth-picks;
Water.

The shear-valve is in contact with the sample blood. Wear gloves while cleaning the shear-valve. Handle the materials use to clean the shear-valve as potentially infectious material.

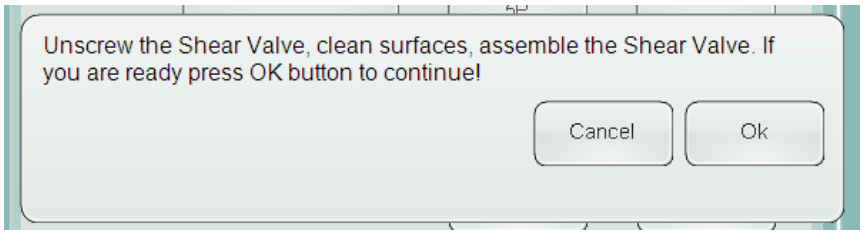
The parts which should be disassembled / re-assembled are fixed with so called thumb-screws. No screwdriver or other similar tool required to tighten these screws.

Go to the Maintenance menu, and select Shear Valve Clean function to initiate the procedure.



The ‘Hemolyzer 5’ asks for confirmation to start the procedure. After clicking/ tapping the ’OK’ button the ‘Hemolyzer 5’ empties the shear-valve and the connecting tubes. Some liquid can remain inside the tubes and inside the shear-valve.

As the preparations completed the ‘Hemolyzer 5’ displays the following message:



Don’t press the ‘OK’ until the shear valve is assembled again!

Perform the shear-valve cleaning according to the instructions below!

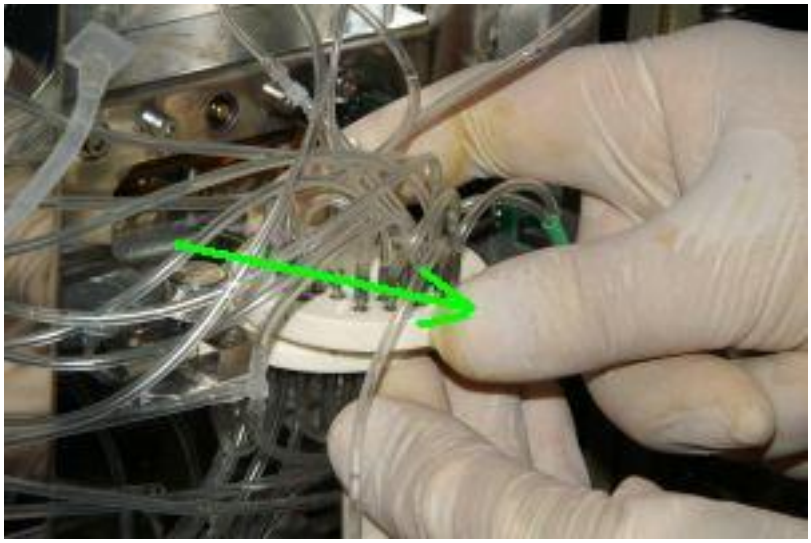
(Below instructions are valid for analyzers manufactured **before** August 2010)

1.: Open the front cover, and secure it with the latch; Locate the shear valve;

2: Unscrew and remove the “Axis screw”

Clean the “Axis screw” by using water and wipe it dry.

3: Slide down the upper disk of the shear valve. Due to the extremely smooth surface of the ceramic discs it is not possible to simply lift up the upper part. If the shear-valve was not in use over a few days, then apply a few drops of water to the contact of the upper and lower disks.



4: Clean the connecting surfaces of the disks of the shear-valve, the housing of the valve, the tube connections. Remove any salt-built-ups. Use the tweezers to push-in the dampened and the dry cloths. You may apply a few drops of water to soften-up the contaminations. You may use a tooth-pick to remove salt-crystals from narrow places. Do not use any sharp/ metal / hard object which can scratch the surface of the shear-valve.

Clean the surrounding and the housing/ mounting of the shear-valve as well if necessary. Pay attention to clean the aligning surface.

Be sure that no lint/ fibers remain on the connection surfaces of the ceramic disks.

5: After cleaning the shear-valve, the housing and surrounding area, put the disks together.

6: Put the “axis screw’ into the upper disk. Gently press and rotate the “axis screw” until it sinks into the upper disk until the shoulder.

7: Firmly push down the “axis screw” against the spring and start to screw it in. Before fastening tight the “axis screw”, be sure that the grooves on the disks positioned similar to the position on the picture.

Fasten the “axis screw hand-tight. (You will clearly feel if you reached the end of the screw.) The spring adjusts the compressing force; you can’t block the movement of the shear-valve by over tightening the “axis screw”.

8: Clean the surrounding of the shear-valve again. You can let the salt crystals and other small parts to fall down. Sweep any particles at the bottom of the ‘Hemolyzer 5’ though the ventilation holes. Remove the gloves. Close the front door. Click/ tap the ‘OK’ button: this informs the ‘Hemolyzer 5’ that you completed the operation.

15.1.6.1 Shear valve with one circle of nozzles

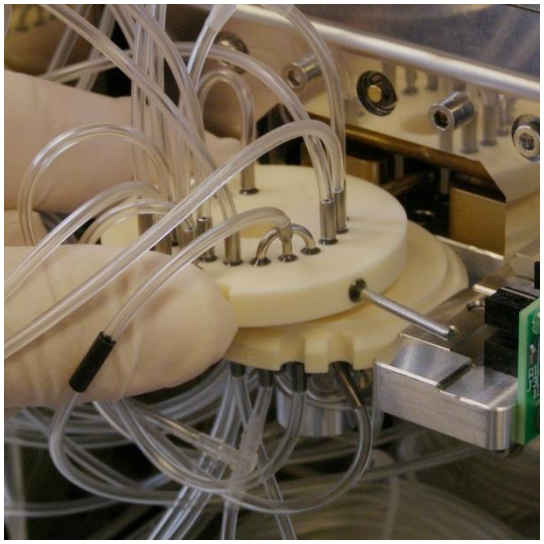
Any salt build-up on the inner surface of the shear-valve may cause malfunction during operation. **To avoid this problem, it is recommended to clean the shear valve after every 1500 samples.**

(Below instructions are valid for analyzers manufactured **after** August 2010)

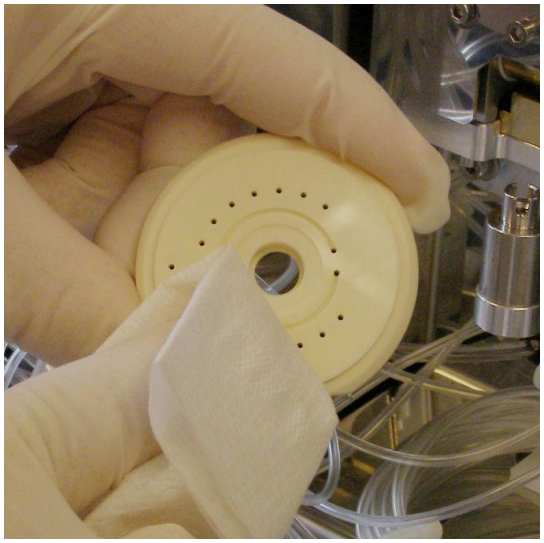
1.: Open the front cover, and secure it with the latch and locate the shear valve (it is in the center of the analyzer.

2: Unscrew and remove the “Axis screw”

Clean the “Axis screw” by using water and wipe it dry.



3: Slide off the upper disk of the shear valve. Due to the extremely smooth surface of the ceramic discs it is not possible to simply lift away the upper part. If the shear-valve was not in use for a few days, then apply a few drops of water to the contact of the upper and lower disks. With time the salt will get dissolved and the upper disk gets released.



4: Clean the connecting surfaces of the disks of the shear-valve, the housing of the valve, the tube connections. Remove any salt-built-ups. Use the tweezers to push-in the dampened and the dry cloths. You may apply a few drops of water to soften-up the contaminations. You may use a tooth-pick to remove salt-crystals from narrow places. Do not use any sharp/ metal / hard object which can

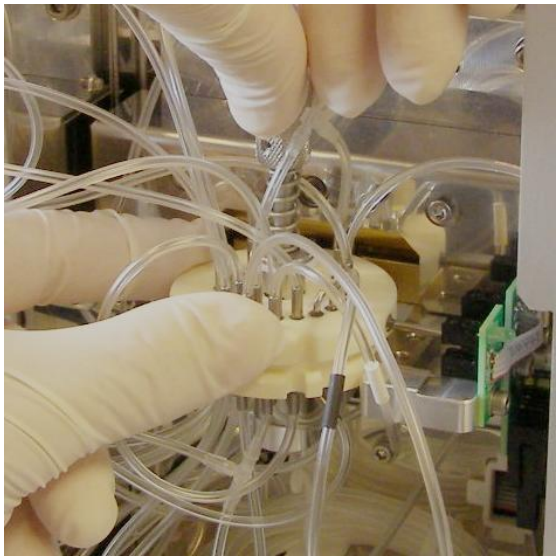
scratch the surface of the shear-valve.

Clean the surrounding and the housing/ mounting of the shear-valve as well if necessary. Pay attention to clean the aligning surface.

Be sure that no lint/ fibers remain on the connection surfaces of the ceramic disks.

5: After cleaning the shear-valve, the housing and surrounding area, put the disks together.

6: Put the “axis screw’ into the upper disk. There is a spring applied to the axis screw. This will guarantee the necessary closing force for the two disks. Gently press and rotate the “axis screw” clockwise until it clicks into the lower part.
Twist the axis screw until it stops. The mechanical design of the screw prevents over-tightening.

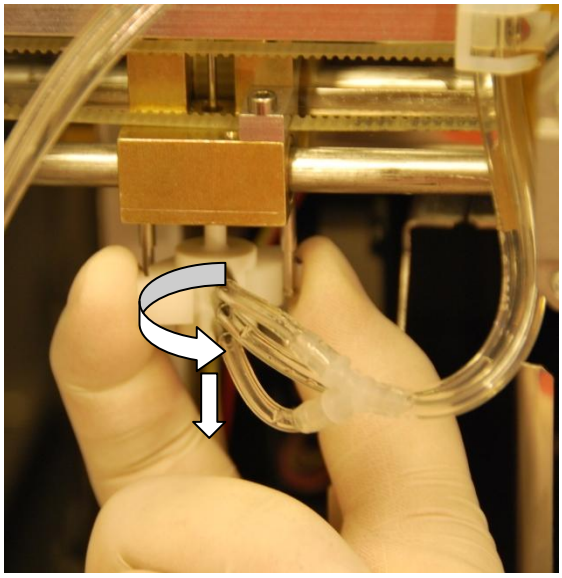


8: Mop the surrounding of the shear-valve again. You can let the salt crystals and other small parts fall down. Sweep any particles at the bottom of the ‘Hemolyzer 5’ though the ventilation holes. Remove the gloves. Close the front door. Click/ tap the ‘OK’ button: this informs the ‘Hemolyzer 5’ that you completed the operation.

The ‘Hemolyzer 5’ will check the movement and end-positions of the shear-valve.

15.1.7 Cleaning the Washing Head

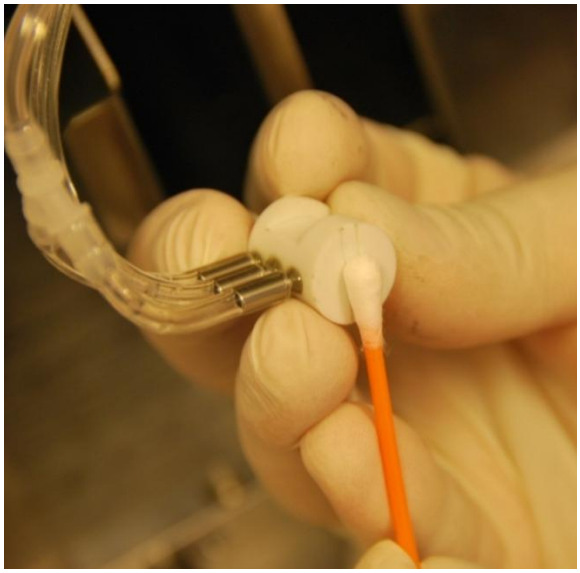
The washing head cleans the outer surface of the aspirating tip with diluent. Any salt build-up on the lower surface may cause malfunction during operation. The wash head must be removed from the needle assembly for correct cleaning.



Open the front panel, and secure it with the support bar. The right side panel of the analyzer must be removed to access the wash head. Loosen the 2+2 screws on the front and rear of the side panel. The panel can be pulled off the analyzer.

Locate the sampling needle. Be careful! The sampling needle is sharp, and can cause injury!

The wash head should be “twisted off” from the needle, and pulled off downwards. Use a soft cloth dampened with water to clean the bottom of the wash head.



To put the wash head back:

Push the wash head onto the needle. Push it up as much as you can (taking care of the sharp needle) and lock it back by twisting it into the grooves of the holding rods.

Replace the side cover and close the front panel.

15.1.8 Cleaning The Measuring Chambers (Hard Cleaning)

If the system keeps reporting high blank values, direct cleaning of measuring chambers must be carried out.

Open the front panel, and secure it with the latch. Remove the left side panel. Loosen the 2+2 screws on the front and rear of the side panel. The panel can be pulled off the analyzer.

Locate the measuring chambers. Using a pipette, inject 1ml of Hypocleaner into each chamber as instructed by the software. Follow instructions on screen. (See Hard Cleaning).

15.1.9 Daily Cleaning

At the end of the daily routine (during shutdown), the analyzer software will ask for a sample vial filled with Hemolyzer-Hypocleaner as a sample. This will clean the whole measurement related tube path.

EVEN THOUGH HEMOLYZER 5 CAN PIERCE THE CAP OF A SAMPLING TUBE, THE RUBBER CAPS ARE NOT DESIGNED FOR MULTIPLE PUNCTURES. THEREFORE IT IS RECOMMENDED TO REMOVE THE CAP OF THE VIAL WITH THE CLEANING SOLUTION, OTHERWISE THE RUBBER WILL HARDEN UP, AND SMALL PARTICLES WILL FALL INTO THE SOLUTION WHICH CAN CAUSE CLOGGING IF ASPIRATED BY THE SAMPLING NEEDLE.

After this operation, you can leave Hemolyzer 5 on for the rest of the day. It will go into a low power state after a specified time.

15.1.10 Special Cleaning Procedure

Despite regular cleaning, Emergency cleaning procedure is advisable, if the blank measurement result is too high or unacceptable result appear during the measurement or calibration.

Use the built-in cleaning process in the maintenance/prime and clean/clean menu and check the proper result with a blank measure.

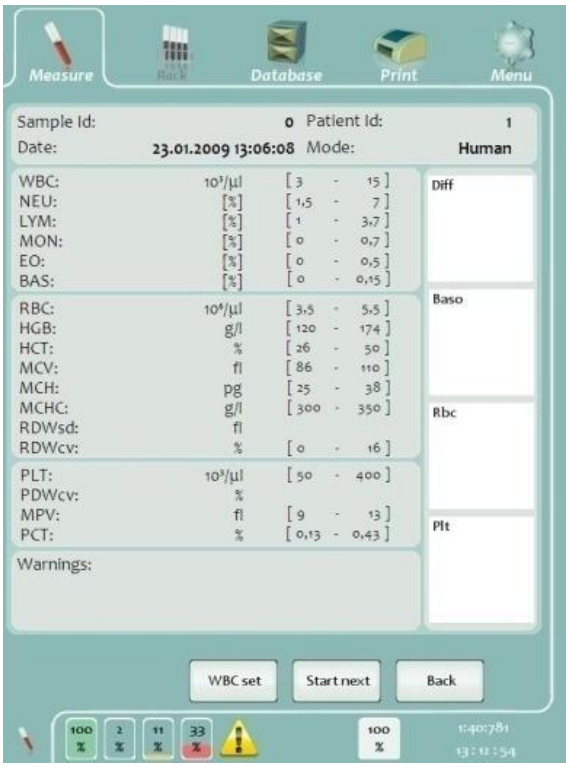
If the blank is still too high use the built-in hard clean process and check the proper result with some blank measures..

If the blank is still too high use the built-in internal diluents reservoir cleaning process and check the proper result with some blank measures.

15.1.11 Replacing Reagents

Hemolyzer 5 is designed to be able to run continuously without the need to stop if a reagent container needs to be replaced. To support this feature, internal buffers keep regents sufficient for one measurement cycle.

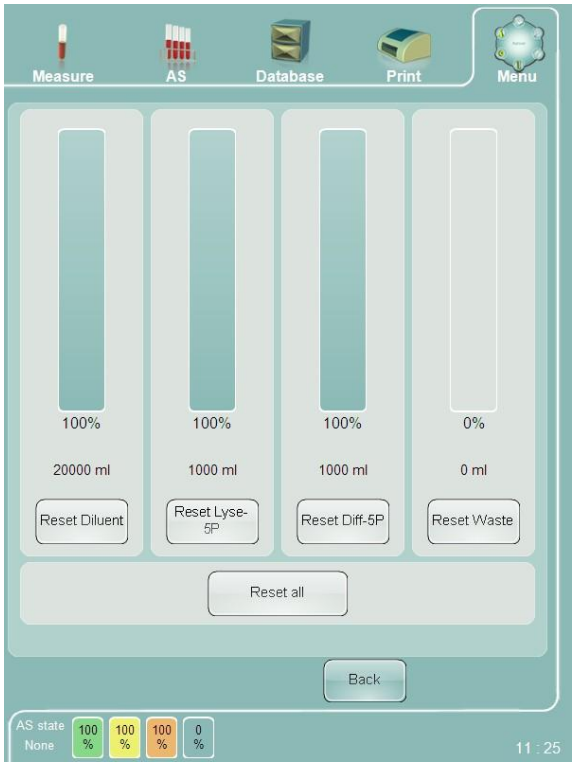
The analyzer will warn the user when a reagent is about to run out. An exclamation mark within a yellow triangle will be displayed by the reagent level indicator.


Measure
Rack
Database
Print
Menu
Sample Id: 0 Patient Id: 1
Date: 23.01.2009 13:06:08 Mode: Human
WBC: 10³/µl [3 - 15]
NEU: [%] [1,5 - 7]
LYM: [%] [1 - 3,7]
MON: [%] [0 - 0,7]
EO: [%] [0 - 0,5]
BAS: [%] [0 - 0,15]
RBC: 10⁶/µl [3,5 - 5,5]
HGB: g/l [120 - 174]
HCT: % [26 - 50]
MCV: fl [86 - 110]
MCH: pg [25 - 38]
MCHC: g/l [300 - 350]
RDWsd: fl
RDWcv: % [0 - 16]
PLT: 10³/µl [50 - 400]
PDWcv: %
MPV: fl [9 - 13]
PCT: % [0,13 - 0,43]
Warnings:
Diff
Baso
Rbc
Plt
WBC set
Start next
Back

To facilitate replacement, “double tapping” on the exclamation mark takes you to an explanation screen. Pressing the “Go to..” button will take you further to the reagent status screen.

To replace reagent containers:

- Prepare the new container, and place it near the place of operation.
- Open the bottle (remove cardboard flaps if necessary (5L and 20L containers).
- Unscrew the cap from the used container and place it into the new container
- Switch the old and new containers
- Dispose of used containers according to local regulations.



When a reagent is replaced, it is not enough to replace the external container only, the reagent level counter must also be reset.

Push the button below the corresponding reagent bar to reset its level back to 100%.

15.1.12 Disposal Of Reagent Containers

Always follow local regulations of hazardous waste disposal

16 Reagent Locking

Reagent locking is a commercial feature of the 'Hemolyzer 5' ensuring that only manufacturer recommended and approved reagents are used with the analyzer. This way analyzer performance cannot be impaired by incompatible reagents. All necessary hardware and software elements are installed and configured on each 'Hemolyzer 5' unit individually.

Each Hemolyzer-5-Lyser (HE5101 - 5 L) reagent bottle comes with a reagent key. The key is in a plastic bag glued to the tear-open flap of the cardboard box container. Each key contains license for 800 measurements.

82. Figure Reagent key inside the Lyse cardboard box

With active 'reagent lock' there is an administrative limit of measurements run on the 'Hemolyzer 5'. The 'Hemolyzer 5' keeps track of the number of measurements performed. If the limit is reached, then the 'Hemolyzer 5' will first warn the user about the fact, then it will refuse to perform further measurements.

The analyzer decreases the number of available measurements with each sample run, even Blank, Calibration and QC measurements. When the counter decreases below 50, and any sample run is started, the user will receive a warning message about this counter decreasing. When the number available reaches zero, the analyzer will not run more samples.

83. Figure Reagent Lock socket

To increase the number of 'remaining' measurements, you have to upload measurement licenses from the hardware-key to the 'Hemolyzer 5'. The uploading can be initiated during 'Lyse' reagent level reset. See chapter 14.1.3;

The hardware-key is similar to a USB memory device but it is not a real USB memory device. Do not insert it into a USB connector. (The hardware key will not harm USB ports, however it can't be predicted how the USB drivers react if a hardware-key is connected as USB device).

To transfer measurement licenses to the 'Hemolyzer 5':

- Remove the hardware key from its protective packaging.
- Insert the hardware-key into the HK-connector close to the stand-by button on the rear of the analyzer (see chapter 4.3.1);
- Initiate 'Reset' of 'Lyse' reagent and follow instructions on the screen;
- All (800) measurement licenses will be transferred from the key to the analyzer.
- Remove the hardware-key from the 'Hemolyzer 5'.

An already used (empty) hardware key cannot be used again

- Collect and return them to your dealer/ service personnel/ sales representative for re-cycling OR dispose of them as electronic waste adhering local regulations.

17 The Daily-Routine

In this chapter a typical daily routine is described. Of course your daily routine can differ from the one described here. This chapter also contains some trick and trips.

The below assumes that the laboratory works during ‘office hours’ only.

The daily routine:

- Power-up, and start-up the ‘Hemolyzer 5’. See Chapter 6.2.2. for details;
- Perform the pneumatics initialization and blank measurement (tap the sampling tube icon)
- Check reagent levels, start your internal procedure to get new reagents from the storage if necessary;
- Collect the samples:
- Check if the correct (K3-EDTA) tubes are used;
- Check if the samples are within the 6 hours of processing limit
- Check if the samples are at room-temperature (refrigerated samples);
- Power on the Autosampler (if installed);
- Perform the QC procedure as scheduled;
- Start the measurements in manual or automated mode. See chapter 7 for details;
- Check and release the results according to your internal regulations;
- Perform the necessary maintenance actions. See chapter 17 for details;
- Shut down the instrument. See chapter 6.3 for details;
- Clean the instrument. See chapter 4.3.

Notes:

Blank measurements:

If you want to check whether the reagent-path was contaminated during the reagent replacement then perform 4-5 blanks measurements before accepting the blank result. The reagents from the internal reservoirs should be used before the new reagent reaches the measurement system;

If you receive the samples in batches and more than 2 hours elapsed between the last sample of the previous batch and the first sample of the next batch, then it is a good practice to repeat the blank measurement;

Quality Control:

Perform QC measurements according to your local regulations;

Please monitor the expiration date and stability after first use of the QC material;

If there are more hematological instruments in your laboratory then it is also a good practice to measure the same human sample on all the instruments to compare the instruments. Use multiple parallel runs to reduce the effect of random error (CV%);

We suggest performing at least one blank measurement before starting QC measurements;

Calibration:

Calibrate the 'Hemolyzer 5' according to laboratory regulations.

Calibration is due with every new control material lot. Also, if QC results or comparison of results to other instruments' results shows permanent error in measurements;

If you perform a measurement based calibration then it is recommended to run a blank measurement before the calibration procedure;

See chapter: 10;

Cleaning:

Perform cleaning / hard cleaning if:

High blank results experienced;

Clogging related flags are added systematically to measurement results;

After service actions, service level maintenance;

Measurement results, QC results are drifting (perform hard cleaning);

Clog formation in the tubing (first remove the plugging, contamination);

Reagent connected to wrong place, wrong reagents were used.

18 Troubleshooting

Your Hemolyzer 5 software is equipped with all the functions to keep the analyzer in good working conditions. Despite careful planning and SW features, the analyzer can still encounter problems where user interaction is required or the user needs to be informed of situations when further help is required.

These are called error messages. Error messages can be further classified. Your analyzer will provide all details to identify the error – however most of the times these errors will be composed of numerical codes. These are important for the service personnel – they can interpret the messages and take necessary actions.

Would you receive error messages with codes, please write them down. If possible, describe with a few words what you were doing before the error came up. This is important so that your service engineer can help you when necessary. The software memorizes every error, but it cannot describe the operation you performed.

When an error comes up, the software will most of the times try to offer solutions, or will try to resolve the problem and retry the current operation. If this recovery process fails, or the problem keeps coming back, please contact your service engineer.

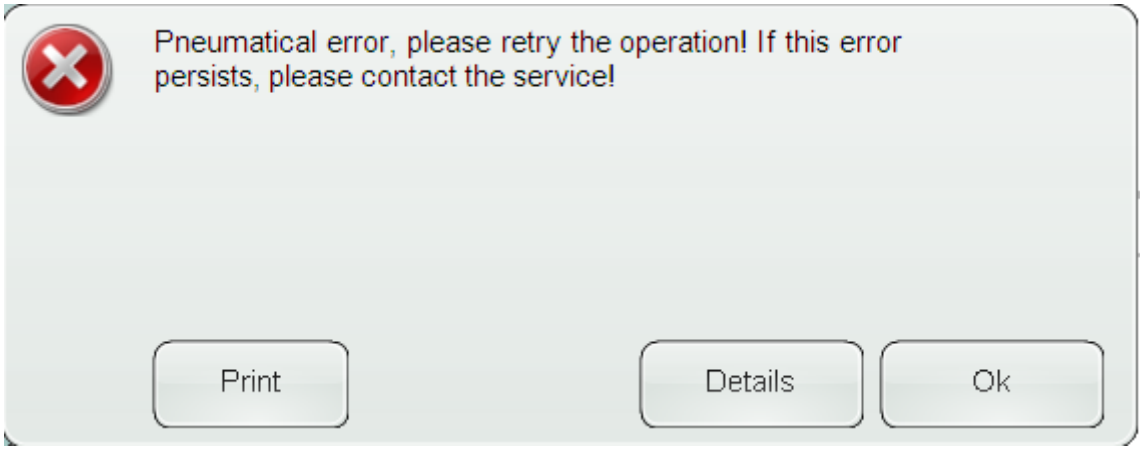
18.1.1 Software error messages

If Windows® XP® Embedded operation system errors come up, please accept the error message and repeat the operation. If there are any other errors please restart the Hemolyzer 5. At the next service visit, please let the service engineer know about the problem.

Low level error messages provide status information about data acquisition system and pneumatic system. Each Error message includes the affected part and the area of the equipment. Check this area and part to find any irregularities like clogging, mechanical problems, blocked elements. Try to repeat the operation. The system will try to recover from the failure. Would it not go away, please contact your service personnel.

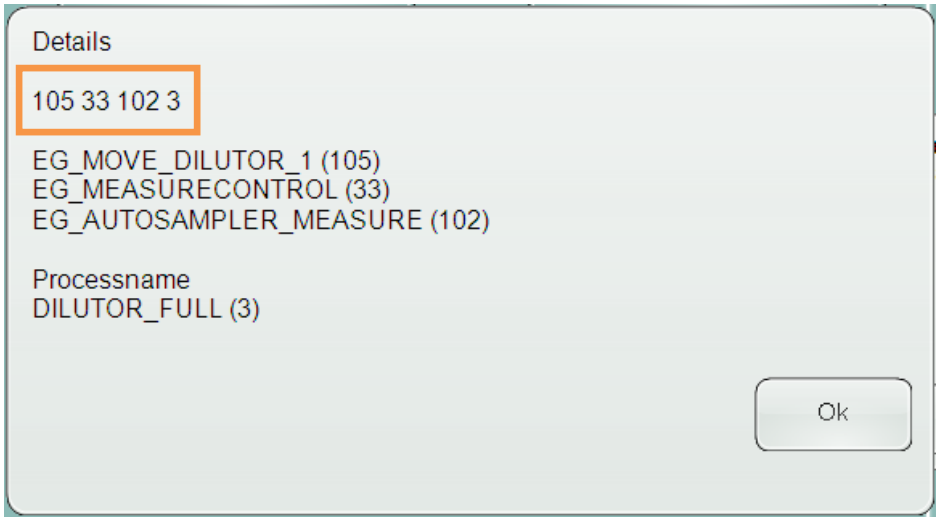
18.1.2 Pneumatic error messages

The analyzer software is designed to be error tolerant, and as such it is able to deal with minor problems. However, if some physical obstructions or extreme operating conditions cause some mechanical parts to behave unexpectedly, the system will give you an error message:



With the OK button, you can return to the current operation and retry the actual process.

You can also tap on the Details button and there you will be able to get further informaion abou the error. It will describe additional conditions of the failure. The numbers in the second row are important for the service personnel.



18.1.3 Mechanical Problems

Most mechanical problems arise because of some physical blockage of the moving parts. Problems caused by severe blocks are most often accompanied by a grinding noise. The noise is a result of a motor not being able to move – however most of the time this will not cause mechanical damage to moving parts.

Typical situations can be traced back to salt build-ups around the wash head or the shear valve. Incorrect operation of cleaning of the system – especially after long inactive periods of time can cause valves or tubes to get filled with somewhat dried salt. These problems can be the sources of dilutor motor noise.

In extreme tube or valve clogging situations the pressure built inside the dilutors can cause some tubes to be released from their connections. This symptom is not normal, but will not cause damage to the system. However, it is recommended to contact Service Personnel to sort out the cause and resolve these problems.

18.1.4 Sample Rotor (SR) Failures

18.1.4.1 SR Gives Grinding Noise And / Or SW Displays SR Error Messages

- the front panel is not closed properly:
  - the opening does not match with the sample rotor door
- there is liquid in the SR, if you can see traces of salt around the SR, contact Service
- check the washing head for contamination (blood and salt) as excessive salt build up can prevent the wash head to lift up effectively and the sample rotor door can get stuck

18.1.4.2 SR Error Appears During Initialization Process:

- check the washing head for contamination (blood and salt)
- contact Service

18.1.4.3 The SR Does Not Turn Into The Analyzer Even With Open Front Panel

- check the washing head for contamination (blood and salt)

18.1.5 Needle Mechanics, Vertical Motor (Mvert) Problems

18.1.5.1 The Needle Carriage Keeps Dropping Back (Down) At Initialization

- Is the wash head and its surrounding free of any salt build-ups?
- salt build up, or thick salt layer at the bottom or on the inside can block the movement of the needle in the wash head (or the movement of the wash head around the needle if you like)
- The through hole of the needle in the vertical carriage should be free of salt.
- salt around the needle can even damage the needle and can influence the sampling process, or sampling quality or amount of sample
- The wash head position relative to the needle and to the SR is not correct
- the wash head comes down too much, and even if lifted, leaves no room for the SR door to turn
- The vertical rod holding the wash head (if removed or modified) is not inserted correctly. The rod was not pushed up to the maximum, and the wash head is sitting in a position too low.

18.1.6 Shear Valve (SV) Related Errors

18.1.6.1 SV Error At The First Startup

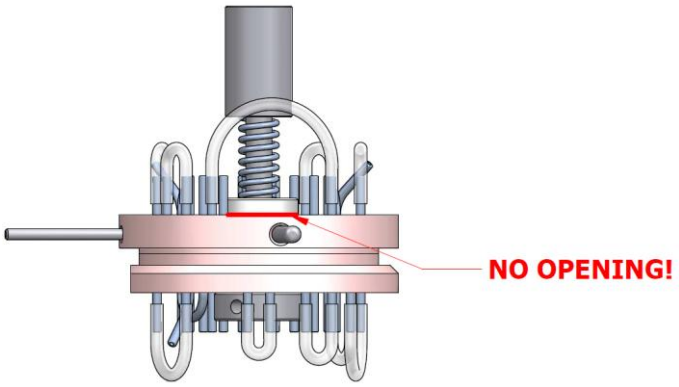
- the SV cannot turn
  - make sure that the pull tab has been removed
  - check free movement by hand (rotate the shear valve)
- The SV is stuck
  - try to open the Shear Valve

18.1.6.2 Grinding Noise After SV Cleaning, (After SV Reinstallation)

- the rotating part cannot reach opto position
- the lower disc is not aligned correctly – see section SV cleaning
  - contact service for guidance

18.1.6.3 SV Leakage

- the upper disc is not sitting well on the lower disc
- open, and reseat the upper disc
- there must not be any opening left between the closing screw and the upper disc



18.1.7 Dilutor Errors

- pinched, clogged tube around dilutor or at the rear reagent tubes
- physical obstruction (foreign material)

18.1.8 Priming Problems

18.1.8.1 The Analyzer Would Not Prime Liquids

- The respective reagent is out
- aspirating tube (in container)
  - has fallen off,
  - has a leakage
  - is broken
- a reagent puffer is leaking… look for liquid below the analyzer
- damaged tube in the system… look for leakage, or traces of liquid, contact Service

18.1.9 Electronics Related Problems

18.1.9.1 No Image On Display, No Backlight

- contact Service

18.1.9.2 Touch Sensitive Surface Not Working

- connect an external USB mouse
    - this will allow clicking on the screen elements
    - contact service for resolution of the problem

18.1.9.3 Touch (Click) Is Inaccurate

- the touch screen needs calibration
- connect an external USB mouse
    - perform the calibration under Main Menu / Maintenance / Touch screen calibration

18.1.9.4 The Cursor Seems To Be Moving With Good Ratios, But In A Smaller Area

- try to calibrate the touch screen. (Use a mouse to access the functions)
- If the problem persists, contact service

18.1.10 The Analyzer Does Not Power On

- Check proper power connections, and the state of the (small) switch at the power supply
- If the above fails, contact Service

18.1.11 I2c Errors Displayed At Startup

- Contact Service

18.2 Measurement results related problems

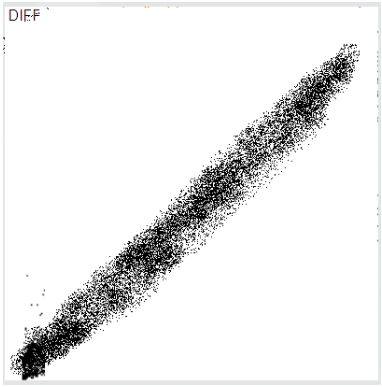
18.2.1 Fluctuating PLT background values

When the Hemolyzer 5 is used under increased workload, running even 300 samples a day (meaning 5 hours of continuous operation) is possible.

Despite built-in maintenance programs, the system may require intensive cleaning from time to time. If you find that Blank PLT values are increasing and decreasing unprecedentedly, please run a “Hard Cleaning” function.

Go to Main Menu, Maintenance. Tap the Hard Cleaning button to initiate the procedure. You will need a syringe (10ml) to dose cleaning liquid into the analyzer’s measuring chambers. The process is described below.

18.2.2 Long, smeared population



This image shows that neither the TCU, nor the reagents, nor the mixing cannot do their jobs.

Possible reason:

- the two lyse reagents are interchanged.
- check tube connections, or container connections

19 Accessories

The following items can be found along with the analyzer.

- Power cord
- Reagent tube kit
- Cleaning tube kit
- Waste container (20L)
- Cardboard box for waste container
- Sample tube adapter
- User’s manual

20 Known Problems

The following problems are known at the time of the releasing of the software and this user manual:

- Long Sample ID is not visible on printout and on display.
- Tooltip info contains square character instead of upper index 6/9/12.
- Sometimes the AS menu is not deactivated when AS is switched off.
- On-screen keyboard remains active while screensaver is running.
- It is necessary to login in multiuser mode to call the shutdown procedure.
- The user is able to log out during pneumatic activities.
- Naming conventions.
- Number of digits on the QC is different.
- The length of some language nodes are longer than expected.
- Patient's SSN is not printed on normal printout.
- If patient data isn't filled out the software could display 'NULL' value.
- Only English characters are accepted as user name.
- Querying statistics/Printing results/Saving to tab separated file is not recommended if more than few hundred results are selected in database view.
- It is not able to print imported data in table view format.

These problems will be fixed in upcoming SW releases.

21 Appendices

21.1.1 Reagent Consumption

Function	Reagent consumption / function (ml)		
	Hemolyzer-Lyser	Hemolyzer-5-Diff 5P	Hemolyzer-Diluent
StartUp	15	2	128
Measure Blank	7	1	52
Measure 5 part	7	1	52
Measure Calibration	7	1	52
Measure QC	7	1	52
Standby	0	0	11
Wakeup	1	0	9
Cleaning	8	1	91
Hard cleaning	8	1	108
Flow cell cleaning	0	0	63
Shear Valve cleaning	10	1.5	100
Offline (overnight) rinsing	8	1	72
**Prime Diluent (full)	0	0	103
**Prime Lyse	7.5	0	2.5
**Prime Diff5P	0	4	0
**Prime all	22	11.5	103
*DrainDilu	0	0	120
*DrainLyse	60	0	0
*DrainDiff5P	0	60	0
*DrainAll	60	60	180
FillUp	22	11.5	103
Shutdown	9	1	111

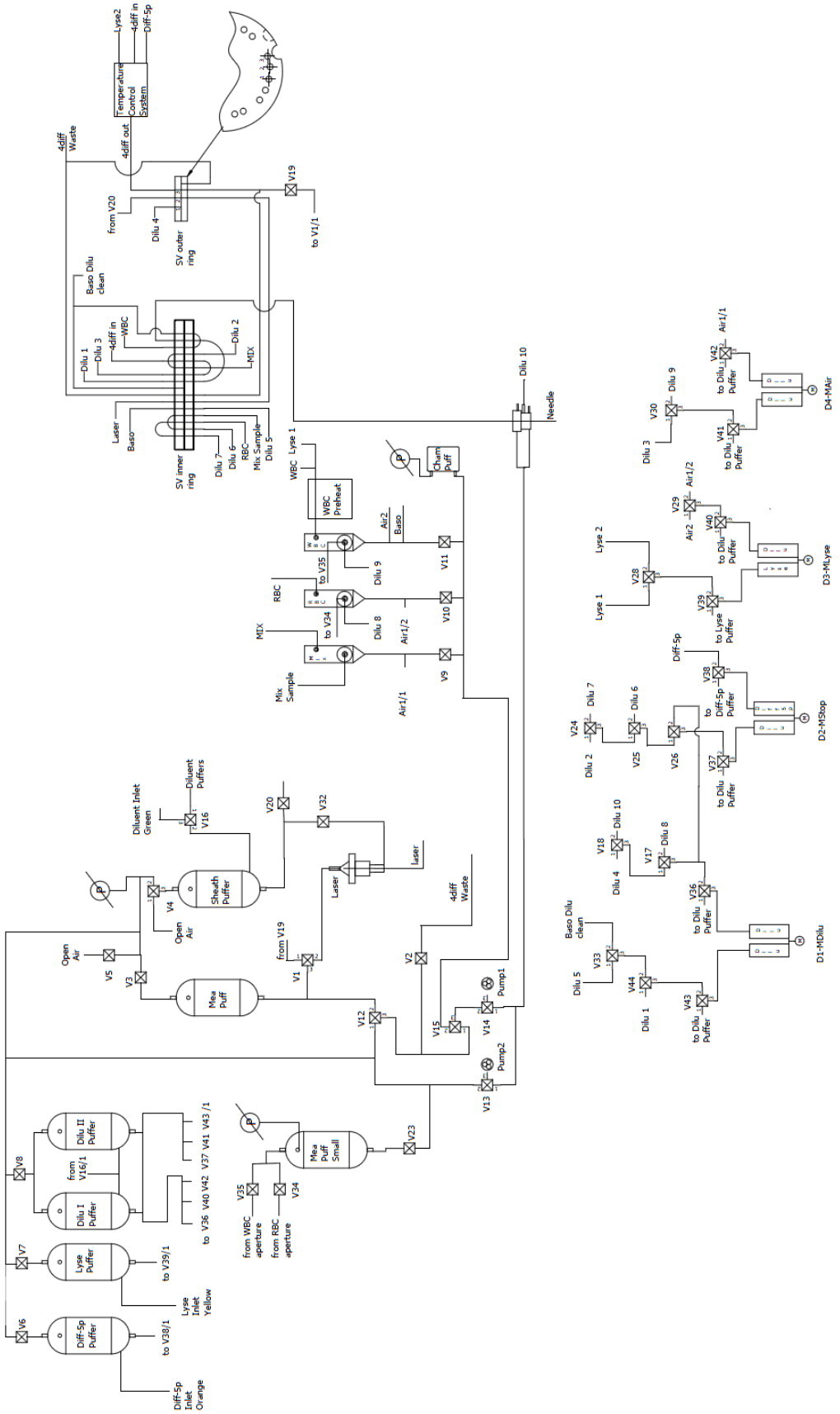
* If internal chambers are filled (volume of chambers: 50 ml each, diluent 2x50 + 50 sheath)

** Prime functions fill internal chambers. The following pneumatic function uses reagents from the inside puffer while the inside puffer is continuously refilled to a steady level.

21.1.2 Display Range

Parameter	Range	Selectable Dimensions
WBC	1.00 – 99.99 * 10^3 / µl	cells/l, cells/µl
RBC	0.00 – 9.99 * 10^6 / µl	cells/l, cells/µl
HGB	0 – 300 g/l	g/dl, g/l, mmol/l
HCT	0 – 100%	percentage, absolute
PLT	0 – 9999 * 10 / µl	cells/l, cells/µl
NEU%	0 -100%	
LYM%	0 -100%	
MON%	0 -100%	
EOS%	0 -100%	
BAS%	0 -5%	
NEU	0.00 –99.99*103 / µl	
LYM	0.00 – 99.99*103 / µl	
MON	0.00 – 99.99*103 / µl	
EOS	0.00 – 99.99*103 / µl	
BAS	0.00 – 4.99*103 / µl	

21.1.3 Fluidic System



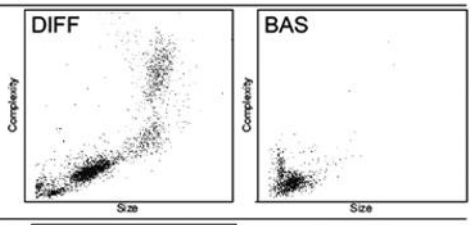
21.1.4 Printed Report Formats

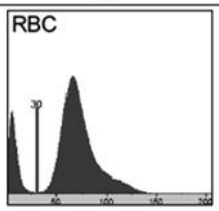
analyticon

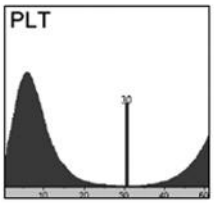
Lab header 1

02/02/2011 12:43

Lab header 2							Lab header 5		
Lab header 3							Lab header 6		
Lab header 4							Lab header 7		
Sample ID	11						Patient ID	1	
Date	10/01/2011 15:54						Name	John Doe	
Mode	Human						Date of birth	23/01/1981	
							Gender	Male	
Parameter	Result			Limit					
WBC	6.15		$10^3/\mu L$	3.50	-	10.00			
NEU	1.28		20.8 %	1.20	-	8.00			
LYM	4.02		65.3 %	0.50	-	5.00			
MON	0.62		10.1 %	0.10	-	0.80			
EO	0.15	-	2.4 %	0.20	-	0.90			
BAS	0.09		1.4 %	0.00	-	0.30			
RBC	3.94		$10^6/\mu L$	3.50	-	5.50			
HGB	90	-	g/L	115	-	165			
HCT	29.0	-	%	35.0	-	55.0			
MCV	73.8	-	fL	75.0	-	100.0			
MCH	22.8	-	pg	25.0	-	35.0			
MCHC	310	++	g/L	31	-	38			
RDWsd	39.9	-	fL	51.0	-	82.0			
RDWcv	13.3		%	11.0	-	16.0			
PLT	501	+	$10^3/\mu L$	100	-	400			
PDWcv	40.5		%		-				
PDWsd	16.5		fL		-				
MPV	7.3	-	fL	8.0	-	11.0			
PCT	0.37		%		-				







Warning flags

Morphological flags

Interpretive flags Microcytic RBC?, Hyperchromic?, Thrombocytosis?, Microcytic PLT?

Doctor

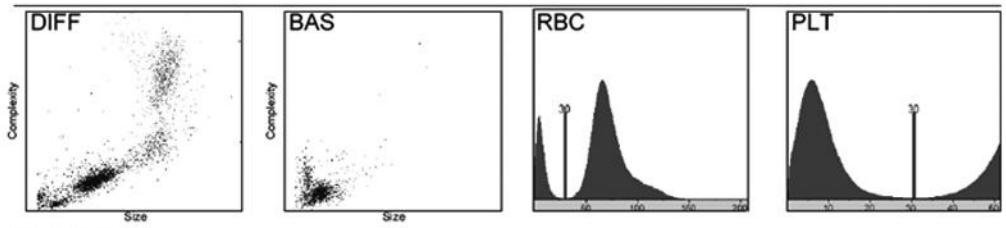
analyticon

Lab header 1 02/02/2011 12:44

Lab header 2
Lab header 3
Lab header 4
Lab header 5
Lab header 6
Lab header 7

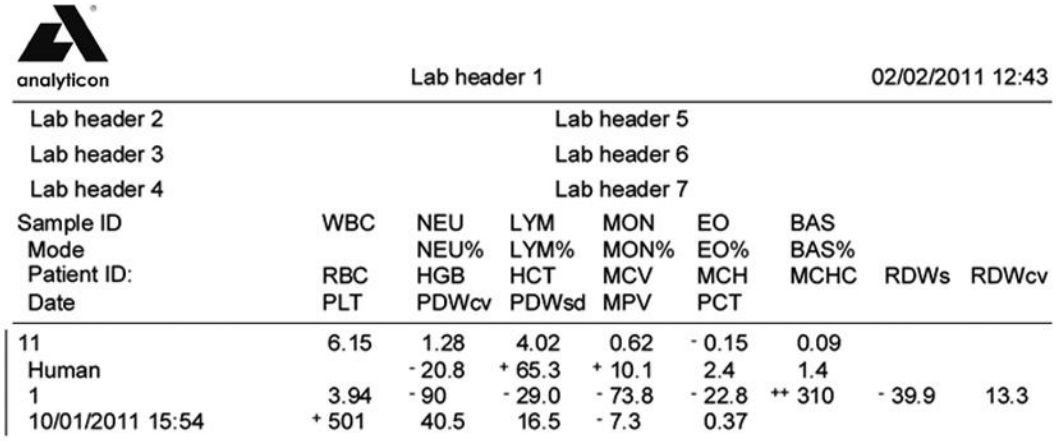
Sample ID 11
Patient ID 1
Date 10/01/2011 15:54
Mode Human

Parameter	Result		Units	Limit
WBC	6.15		$10^3/\mu L$	3.50 - 10.00
NEU	1.28		$10^3/\mu L$	1.20 - 8.00
LYM	4.02		$10^3/\mu L$	0.50 - 5.00
MON	0.62		$10^3/\mu L$	0.10 - 0.80
EO	0.15	-	$10^3/\mu L$	0.20 - 0.90
BAS	0.09		$10^3/\mu L$	0.00 - 0.30
NEU%	20.8	-	%	35.0 - 80.0
LYM%	65.3	+	%	15.0 - 50.0
MON%	10.1	+	%	3.0 - 9.0
EO%	2.4		%	1.0 - 8.0
BAS%	1.4		%	0.0 - 2.0
RBC	3.94		$10^6/\mu L$	3.50 - 5.50
HGB	90	-	g/L	115 - 165
HCT	29.0	-	%	35.0 - 55.0
MCV	73.8	-	fL	75.0 - 100.0
MCH	22.8	-	pg	25.0 - 35.0
MCHC	310	++	g/L	31 - 38
RDWsd	39.9	-	fL	51.0 - 82.0
RDWcv	13.3		%	11.0 - 16.0
PLT	501	+	$10^3/\mu L$	100 - 400
PDWcv	40.5		%	-
PDWsd	16.5		fL	-
MPV	7.3	-	fL	8.0 - 11.0
PCT	0.37		%	-



Warning flags
Morphological flags
Interpretive flags Microcytic RBC?, Hyperchromic?, Thrombocytosis?, Microcytic PLT?

Doctor



analyticon

Lab header 1 02/02/2011 12:43

Lab header 2 Lab header 5

Lab header 3 Lab header 6

Lab header 4 Lab header 7

Sample ID	WBC	NEU	LYM	MON	EO	BAS		
Mode		NEU%	LYM%	MON%	EO%	BAS%		
Patient ID:	RBC	HGB	HCT	MCV	MCH	MCHC	RDWs	RDWcv
Date	PLT	PDWcv	PDWsd	MPV	PCT			
11	6.15	1.28	4.02	0.62	- 0.15	0.09		
Human		- 20.8	+ 65.3	+ 10.1	2.4	1.4		
1	3.94	- 90	- 29.0	- 73.8	- 22.8	++ 310	- 39.9	13.3
10/01/2011 15:54	+ 501	40.5	16.5	- 7.3	0.37			

analyticon

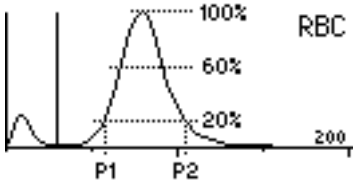
03/06/2010 14:20

Sample ID	Measure type	Patient ID:	Date
WBC			
NEU	LYM	MON	EO	BAS
NEU%	LYM%	MON%	EO%	BAS%
RBC	HGB	HCT	MCV	MCH
MCHC	RDWsd	RDWcv		
PLT	PDWcv	PDWsd	MPV	PCT

ny20489	Human	1		25/01/2010 16:48
-- 5.74				
4.05	-- 1.15	0.35	0.17	0.03
-- 70.5	-- 20.0	6.1	2.9	0.5
-- 4.74	-- 137	-- 0.41	-- 86.8	-- 29.0
-- 334	52.9	12.6		
216	37.1	21.6	-- 10.2	-- 0.002
ny20489	Human	1		25/01/2010 16:49
-- 5.56				
3.95	-- 1.05	0.36	0.17	0.03
-- 71.1	-- 18.9	6.4	3.1	0.5
-- 4.81	-- 137	-- 0.42	-- 87.0	-- 28.5
-- 328	51.2	12.4		
201	37.2	20.6	-- 9.8	-- 0.002
ny20489	Human	1		25/01/2010 16:50
-- 5.45				
3.91	-- 1.02	0.35	0.15	0.02
-- 71.7	-- 18.7	6.4	2.8	0.4
-- 4.77	-- 138	-- 0.42	-- 87.2	-- 29.0
-- 333	50.7	12.2		
238	37.0	21.6	-- 10.2	-- 0.002
ny20489	Human	1		25/01/2010 16:51
-- 5.52				
3.84	-- 1.08	0.36	0.20	0.03
-- 69.6	-- 19.6	6.6	3.6	0.6
-- 4.85	-- 140	-- 0.42	-- 87.4	-- 28.9
-- 330	49.6	12.1		
216	37.0	20.3	-- 9.9	-- 0.002
ny20489	Human	1		25/01/2010 16:52
-- 5.49				
3.83	-- 1.08	0.41	0.15	0.02
-- 69.7	-- 19.7	7.5	2.7	0.4
-- 4.78	-- 139	-- 0.41	-- 86.6	-- 29.0
-- 335	49.9	12.1		
224	36.4	20.1	-- 9.9	-- 0.002
ny20489	Human	1		25/01/2010 16:53
-- 5.57				
3.91	-- 1.13	0.36	0.14	0.03
-- 70.2	-- 20.3	6.4	2.5	0.6
-- 4.70	-- 137	-- 0.41	-- 86.6	-- 29.2
-- 337	53.8	12.8		
216	36.6	19.9	-- 9.7	-- 0.002

21.1.5 Specifications

21.1.6 Measured Parameters

White Blood Cells – WBC (cells/l, cells/µl)	Number of leukocytes WBC = WBCcal x (cells/l, cells/µl)
Red Blood Cells – RBC (cells/l, cells/µl)	Number of erythrocytes RBC = RBCcal x (cells/l, cells/µl)
Hemoglobin concentration - HGB (g/dl, g/l, mmol/l)	Measured photometrically at 540 nm; in each cycle blank measurement is performed on diluent HGB = HGBcal x (HGBmeasured – HGBblank)
Mean Corpuscular Volume - MCV (fl)	Average volume of individual erythrocytes derived from the RBC histogram.
Hematocrit – HCT (percentage, absolute)	Calculated from the RBC and MCV values. HCTpercentage = RBC x MCV x 100 HCTabsolute = RBC x MCV
Mean Corpuscular Hemoglobin – MCH (pg, fmol)	Average hemoglobin content of erythrocytes, calculated from RBC and HGB values. MCH = HGB / RBC
Mean Corpuscular Hemoglobin Concentration – MCHC (g/dl, g/l, mmol/l)	Calculated from the HGB and HCT values. MCHC = HGB / HCTabsolute Unit of measurement is displayed according to the one chosen for HGB result (g/dl, g/l or mmol/l)
Red Cell Distribution Width – RDW-SD (fl) Platelet Distribution Width – PDW-SD (fl) Red cell Distribution Width – RDW-CV (absolute) Platelet Distribution Width – PDW-CV (absolute)	The distribution width of the erythrocyte or platelet population derived from the histogram at 20% of peak  xDW-SD = RDWcal x (P2 - P1) (fl), xDW-CV = RDWcal x 0.56 x (P2 - P1) / (P2 + P1) by the factor of 0.56 CV is corrected to the 60% cut
Platelet – PLT (cells/l, cells/µl)	Number of thrombocytes (platelets) PLT = PLTcal x (cells/l, cells/µl)

Mean Platelet Volume – MPV (fl)	Average volume of individual platelets derived from the PLT histogram
Thrombocrit – PCT (percentage, absolute)	Calculated from the PLT and MPV values PCTpercentage = PLT x MPV x 100 PCTabsolute = PLT x MPV
White blood cell, 4 part differential: LYM (%) : lymphocytes MON (%) : monocytes and some eosinophils NEU (%) : neutrophil granulocytes EOS(%):eosinophil granulocytes	Relative value are calculated from the optical 4 diff scatter populations
BAS (%):basophil granulocytes	Relative value is calculated from the basofil optical scatter populations

21.1.7 Technical Data

21.1.7.1 Main Unit

Sample volume	Closed-, and Open-mode: 110 µl
Sample type	Human whole blood (K3-EDTA anticoagulant)
Tube Identification	By means of the front panel keyboard (enter ID)
	By means of the barcode labels (manual and/or auto-sampler)
Sampling method	Ceramic shear valve with 3 separated primary loops
Measured parameters	CBC+5DIFF mode (24 parameters):
	WBC, LYM, MON, NEU, EOS, BAS, LYM%, MON%, NEU%, EOS%, BAS%
	RBC, HCT, MCV, RDWsd, RDWcv HGB, MCH, MCHC
	PLT, PCT, MPV, PDWsd,PDWcv
Throughput	60 tests/hour
Measurement method	Volumetric impedance change for WBC, RBC, PLT
	Spectrophotometry for HGB
	Light scattering 4-diff measurement: LYM, MON, NEU, EOS
	Light scattering BASO measurement
Aperture diameter	WBC: 80 µm, RBC/PLT: 70 µm

Aperture length	WBC: 80 µm, RBC/PLT: 70 µm
HGB measurement	Light source: green LED with 540 nm wavelength
	Detector: light to frequency converter
Optical measurement	Light source: semiconductor laser diode with 650 nm wavelength and 7mW (Class IIIB laser module if the protective housing is closed)
	Quartz flow cell with hydro-dynamic focusing
	Detector: fiber optic coupled PIN Si photodiodes
	Internal safety interlock
Auto-alignment system	Horizontal calibration of laser beam position.
	Fine calibration: with calibration material (Polystyrene micro-particle or Polystyrene microsphere, 5µm)
Reagents	Hemolyzer-Diluent (20 liter)
	Hemolyzer-5-Lyser (5 liter) Hemolyzer-5-Diff 5P (1 liter)
	Hemolyzer Hypocleaner (100 ml) (Emergency cleaner)
Dilution ratios	WBC/BAS 1: 170
	RBC/PLT 1: 21250
	4 DIFF 1: 50
Sheath fluid	Diluent
Control material	D-Check 3P, Manufacturer: R&D Systems
Quality Control	Levey-Jennings charts, QC database
Flagging	Pathological (diagnostic) flags
	Lab limits (normal ranges)
	Reagents alert (3 measurement prealert-online reagent replacement) Instrument alerts, internal puffer for reagents
Calibration	Manual and SW supported automatic mode
Languages available	English menu and support for other languages
Software upgrade	Via USB
Data storage capacity	100.000 records including flags, scatter- and histograms
Data processing	VIA C7 1.8 GHz processor
Data store	Windows® XP® Embedded
Display	800 x 600 color graphic LCD, portrait layout

External printing	Via USB port, any Windows® XP® compatible printer
External keyboard	Via PS/2 or USB
Bar-Code reader	Optional Manual bar-code reader via USB
	Built in Bar-Code in the Auto-sampler
Peripheral ports	USB (2.0) 4pc., Ethernet, PS/2
Power requirements	Power supply input: 100-127VAC/200-240 VAC; 47Hz to 63Hz
	Power Consumption: maximum 400 VA
Main fuse	F 10A H 250V
Operating temperature	15-30° C (59-86 °F);
Maximum relative humidity	80%

Guidelines for transport	The instrument in its export package should fulfill the following transport/storage conditions:

- Does not exceed ‑15°C (5°F) for ≥24 hours.
- Does not exceed a dry heat of 70°C (+158°F) for ≥24 hours.
- Dramatic change of temperature between -15°C (5°F) and 30°C (+86°F).
- Does not exceed a damp heat steady state of 90% RH and 40°C (+104°F) during 48 hours.
- Does not exceed a damp heat cyclic of 90-100% RH and +25°/+40°C (+77°/+104°F) 12+12 hours.

21.1.8 Performance Data

21.1.8.1 Precision

Parameters	CV	Range
WBC	CV ≤ 3%	4.7 * 10^3 / µl ≤ WBC≤ 38 * 10^3 / µl
		All 5 part parameters (NEU, LYM, MON, EOS, BAS abs and %) at 4.7 * 10^3 / µl ≤ WBC≤ 38 * 10^3 / µl
NEU%	CV ≤ 5%	87.4% ≥ NEU% ≥ 47%
LYM%	CV ≤8%	35.6 % ≥ LYM% ≥ 15%
MON%	CV ≤ 20%	16.3% ≥ MON%5.3%
EOS%	CV ≤ 25%	11% ≥ EOS% ≥1.5%
BAS%	CV≤ 40%	2.4 % ≥ BAS% ≥1%
NEU	CV ≤ 5%	NEU%30%
LYM	CV ≤ 8%	LYM%15%
MON	CV ≤ 20%	MON%5%
EOS	CV ≤ 25%	EOS% ≥ 1.5%
BAS	CV ≤ 40%	BAS% ≥1%
RBC	CV ≤ 1.5%	2.5 * 10^6 / µl ≤ RBC≤ 5.44 * 10^6 / µl
HGB	CV ≤ 1.5%	78.5 g/l ≤ HGB ≤ 184 g/l
HCT	CV ≤ 2%	20-49 HCT%
MCV	CV ≤ 1%	65 fl ≤ MCV ≤ 105 fl
PLT	CV ≤ 5%	100 * 10^3 / µl ≤ PLT ≤ 492 * 10^3 / µl
MPV	CV ≤ 5%	5.6 fl ≤ MPV ≤ 11.3 fl

21.1.8.2 Accuracy Values And Ranges

Accuracy	Experienced coefficient Against Reference (Cell-Dyn 3700)	Range
WBC	r = 1.00	$0.5*10^3$ / µl ≤ WBC ≤ $56.3*10^3$/µl
RBC	r = 0.99	$2.2*10^6$ / µl ≤ RBC ≤ $6.3*10^6$/µl
HGB	r = 0.99	68.8 g/l ≤ HGB ≤ 173 g/l
HCT	r = 0.99	19.5% ≤ HCT% ≤ 52.6%
PLT	r = 0.98	$12.5*10^3$ / µl ≤ PLT ≤ $699*10^3$/µl
NEU%	r = 0.99	5.8% ≤ NEU% ≤ 94.6%
LYM%	r = 0.99	2.5% ≤ LYM% ≤ 79.5%
MON%	r = 0.90	1.1% ≤ MON% ≤ 28.1%
EOS%	r = 0.95	0.0% ≤ EOS% ≤ 23.6%
BAS%	r = 0.55	0.1% ≤ BAS% ≤ 4.2%

Note 1: the 5part WBC is not reportable if the total WBC count is below 1 $*10^3$ / µl. (The quantation error grows to high.)

21.1.8.3 Linearity Values And Ranges

Linearity	Coefficient of determination	Range
WBC	r^2 ≥ 0.95	$1*10^3$ / µl ≤ WBC ≤ $100*10^3$/µl
RBC	r^2 ≥ 0.95	0.4 *10^6 / µl ≤ RBC ≤ 7.5 * 10^6/µl
HGB	r^2 ≥ 0.95	13 g/l ≤ HGB ≤ 227 g/l
PLT	r^2 ≥ 0.95	$10*10^3$ / µl ≤ PLT ≤ $873*10^3$/µl

21.1.8.4 Carryover Values And Ranges

Carryover	High-to-low effect	Range
WBC	0.5% or less	LO ≤ $10*10^3$/µl HI ≥ $75*10^3$/µl
RBC	0.5% or less	LO ≤ 2.3* 10^6/µl HI ≥ 7.5* 10^6/µl
HGB	0.5% or less	LO ≤ 90 g/l HI ≥270 g/l
PLT	0.5% or less	LO ≤ 140 *10^3 / µl HI ≥ $730*10^3$ / µl

21.1.9 Reagent System

See chapter 0.

21.1.9.1 Diluent

Hemolyzer Diluent:	Isotonic solution, used to dilute whole blood and quantitative and qualitative determination of RBC, WBC, PLT and HGB concentration

21.1.9.2 Lyser

Hemolyzer-5-Lyser WBC-5Part lysing:	Reagent for stromatolysis of RBC and quantitative determination of WBC 5-part differentiation (LYM, MON, NEU, EOS, BAS) and HGB concentration measurement of human blood.

21.1.9.3 Lyser 2

Hemolyzer-5-Diff - 5Part:	Quantitative determination of WBC, leukocyte four-part differentiation (LYM, MON, NEU, EOS).

21.1.9.4 Cleaner

Hemolyzer Hypocleaner:	Capillaries, tubing and chambers, removing blood component precipitates.

21.1.10 Tab File Format

This file format is composed of a header line and consecutive lines containing records selected for saving. Each parameter is selected by the <TAB> (08h) character, allowing easy interfacing or importing into most data processing applications, like Microsoft® Excel. Scatter diagrams and historgrams, flags are NOT saved in this format.

The header line contains the same column names you can see in the analyzer database.

Data values are saved as they are stored in the analyzer database, alphanumerical or numerical. Decimal separator is defined by the actual operating language of the software.

Example “tab separated file”

ResultID <TAB>Creation time <TAB>Sample Id <TAB>Creation time <TAB>Mode <TAB>WBC <TAB>LYM <TAB>NEU <TAB>MON <TAB>EO <TAB>BAS <TAB>LYM% <TAB>NEU% <TAB>MON% <TAB>EO% <TAB>BAS% <TAB>RBC <TAB>HGB <TAB>HCT <TAB>MCV <TAB>MCH <TAB>MCHC <TAB>RDWsd <TAB>RDWcv <TAB>PLT <TAB>PDWsd <TAB>PDWcv <TAB>MPV <TAB>PCT <TAB>

7538 <TAB>02/04/2009 15:59:05 <TAB>402 <TAB>02/04/2009 15:59:05 <TAB>Human <TAB>70.65 <TAB>56.66 <TAB>2.9 <TAB>11.09 <TAB>0 <TAB>0 <TAB>80.2 <TAB>4.1 <TAB>15.7 <TAB>0 <TAB>0 <TAB>1.83 <TAB>63 <TAB>33.3 <TAB>181.8 <TAB>34.4 <TAB>190 <TAB>75.8 <TAB>16 <TAB>17 <TAB>16.3 <TAB>43 <TAB>8.9 <TAB>0.02 <TAB>

7540 <TAB>02/04/2009 16:11:13 <TAB>402 <TAB>02/04/2009 16:11:13 <TAB>Human <TAB>70.65 <TAB>62.1 <TAB>1.77 <TAB>6.78 <TAB>0 <TAB>0 <TAB>87.9 <TAB>2.5 <TAB>9.6 <TAB>0 <TAB>0 <TAB>1.83 <TAB>63 <TAB>33.3 <TAB>181.8 <TAB>34.4 <TAB>190 <TAB>75.8 <TAB>16 <TAB>17 <TAB>16.3 <TAB>43 <TAB>8.9 <TAB>0.02 <TAB>

7541 <TAB>02/04/2009 16:13:24 <TAB>402 <TAB>02/04/2009 16:13:24 <TAB>Human <TAB>70.65 <TAB>63.09 <TAB>1.7 <TAB>5.86 <TAB>0 <TAB>0 <TAB>89.3 <TAB>2.4 <TAB>8.3 <TAB>0 <TAB>0 <TAB>1.83 <TAB>63 <TAB>33.3 <TAB>181.8 <TAB>34.4 <TAB>190 <TAB>75.8 <TAB>16 <TAB>17 <TAB>16.3 <TAB>43 <TAB>8.9 <TAB>0.02 <TAB>

7542 <TAB>02/04/2009 16:16:53 <TAB>402 <TAB>02/04/2009 16:16:53 <TAB>Human <TAB>70.65 <TAB>64.01 <TAB>1.48 <TAB>5.16 <TAB>0 <TAB>0 <TAB>90.6 <TAB>2.1 <TAB>7.3 <TAB>0 <TAB>0 <TAB>1.83 <TAB>63 <TAB>33.3 <TAB>181.8 <TAB>34.4 <TAB>190 <TAB>75.8 <TAB>16 <TAB>17 <TAB>16.3 <TAB>43 <TAB>8.9 <TAB>0.02 <TAB>

7543 <TAB>02/04/2009 17:31:12 <TAB>402 <TAB>02/04/2009 17:31:12 <TAB>Human <TAB>70.65 <TAB>64.01 <TAB>1.48 <TAB>5.16 <TAB>0 <TAB>0 <TAB>90.6 <TAB>2.1 <TAB>7.3 <TAB>0 <TAB>0 <TAB>1.83 <TAB>63 <TAB>33.3 <TAB>181.8 <TAB>34.4 <TAB>190 <TAB>75.8 <TAB>16 <TAB>17 <TAB>16.3 <TAB>43 <TAB>8.9 <TAB>0.02 <TAB>

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